

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE NATIONAL PRESCRIPTION
OPIATE LITIGATION

This document relates to:

Case No. 1:17-op-45053-DAP (S.D. W.Va.)
and
Case No. 1:17-op-45054 (S.D. W.Va.)

CABELL COUNTY COMMISSION and
CITY OF HUNTINGTON, WEST VIRGINIA,

Plaintiff,

PURDUE PHARMA L.P., PURDUE
PHARMA INC., THE PURDUE FREDERICK
COMPANY, INC., RHODES
PHARMACEUTICALS L.P., RHODES
TECHNOLOGIES, INC., RICHARD S.
SACKLER, M.D., KATHE A. SACKLER,
JONATHAN D. SACKLER, MORTIMER
D.A. SACKLER, ILENE SACKLER
LEFCOURT, BEVERLY SACKLER,
THERESA SACKLER, DAVID A.
SACKLER, ALLERGAN PLC F/K/A
ACTAVIS PLC F/K/A ALLERGAN INC.,
ALLERGAN FINANCE LLC F/K/A
ACTAVIS INC. F/K/A WATSON
PHARMACEUTICALS, INC., ALLERGAN
SALES, LLC, ALLERGAN USA, INC.,
WATSON LABORATORIES, INC.,
WARNER CHILCOTT COMPANY, LLC,
ACTAVIS PHARMA, INC. F/K/A WATSON
PHARMA, INC., ACTAVIS SOUTH
ATLANTIC LLC, ACTAVIS ELIZABETH
LLC, ACTAVIS MID ATLANTIC LLC,
ACTAVIS TOTOWA LLC, ACTAVIS LLC,
ACTAVIS KADIAN LLC, ACTAVIS
LABORATORIES UT, INC., ACTAVIS
LABORATORIES FL, INC., JOHNSON &
JOHNSON, JANSSEN

MDL No. 2804

Case No. 17-md-2804

Judge Dan Aaron Polster

CORRECTED JOINT AND THIRD
AMENDED COMPLAINT

DEMAND FOR JURY TRIAL

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

PHARMACEUTICALS, INC., NORAMCO,
INC., ORTHO-MCNEIL-JANSSEN
PHARMACEUTICALS, INC. N/K/A
JANSSEN PHARMACEUTICALS, INC.,
JANSSEN PHARMACEUTICA, INC. N/K/A
JANSSEN PHARMACEUTICALS, INC.,
ENDO HEALTH SOLUTIONS INC., ENDO
PHARMACEUTICALS, INC., PAR
PHARMACEUTICAL, INC., PAR
PHARMACEUTICAL COMPANIES, INC.
F/K/A PAR PHARMACEUTICAL
HOLDINGS, INC., TEVA
PHARMACEUTICAL INDUSTRIES LTD.,
TEVA PHARMACEUTICALS USA, INC.,
CEPHALON, INC., MALLINCKRODT PLC,
MALLINCKRODT LLC, SPECGX LLC,
KVK-TECH, INC., AMNEAL
PHARMACEUTICALS, LLC, AMNEAL
PHARMACEUTICALS, INC., IMPAX
LABORATORIES, LLC, AMNEAL
PHARMACEUTICALS OF NEW YORK
LLC, AMERISOURCEBERGEN DRUG
CORPORATION, CARDINAL HEALTH,
INC., MCKESSON CORPORATION, CVS
HEALTH CORPORATION, CVS INDIANA
L.L.C., CVS RX SERVICES, INC., CVS
TENNESSEE DISTRIBUTION, L.L.C., CVS
PHARMACY, INC., WEST VIRGINIA CVS
PHARMACY, LLC, RITE AID
CORPORATION, RITE AID OF
MARYLAND, INC. D/B/A RITE AID MID-
ATLANTIC CUSTOMER SUPPORT
CENTER, INC., RITE AID OF WEST
VIRGINIA, INC., WALGREENS BOOTS
ALLIANCE, INC., WALGREEN EASTERN
CO., INC., WALGREEN CO., H. D. SMITH
WHOLESALE DRUG CO., KROGER
LIMITED PARTNERSHIP I, KROGER
LIMITED PARTNERSHIP II, WALMART
INC, WAL-MART STORES EAST D/B/A
WAL-MART PHARMACY WAREHOUSE
#46, WAL-MART PHARMACY
WAREHOUSE #45, WAL-MART
PHARMACY WAREHOUSE, EXPRESS
SCRIPTS HOLDING COMPANY, EXPRESS
SCRIPTS, INC., CAREMARK RX, LLC,

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

OPTUM, INC., OPTUMRX INC.,
TASMANIAN ALKALOIDS PTY. LTD.

Defendants.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

PRELIMINARY STATEMENT	9
PARTIES	18
I. PLAINTIFFS	18
II. DEFENDANTS	21
A. Manufacturer Defendants.....	21
1. Purdue Companies	21
2. Purdue Directors and Officers	24
3. Actavis Entities	30
4. Janssen Entities	35
5. Endo Entities.....	39
6. Cephalon Entities	40
7. Mallinckrodt Entities	41
8. KVK Tech.....	44
9. Amneal Pharmaceuticals.....	44
B. Distributor Defendants.....	45
1. AmerisourceBergen	46
2. Cardinal Health	47
3. McKesson	47
4. H.D. Smith Wholesale Drug Co.	48
5. CVS.....	49
6. Rite Aid.....	54
7. Walgreens	58
8. Kroger	60
9. Walmart Inc.	63
C. National Pharmacies	66
1. CVS	67
2. Rite Aid	67
3. Walgreens	67
4. Walmart.....	68
5. Kroger	68
D. Pharmacy Benefit Managers	69
1. Express Scripts.....	70
2. CVS Caremark	71
3. Optum Rx.....	72
E. Agency and Authority.....	72
JURISDICTION AND VENUE	73
JURY DEMAND	74
FACTUAL ALLEGATIONS	74
I. Facts Common to All Claims.....	74
A. Defendants' Conduct Created an Abatable Public Nuisance.....	74

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

B.	Summary of the Origin of the Opioid Epidemic and Opioid Public Nuisance.....	75
C.	Opioids and Their Effect.....	80
D.	The Resurgence of Opioid Use in the United States.....	83
1.	The Sackler Family Integrated Advertising and Medicine	83
2.	Purdue and the Development of OxyContin.....	85
3.	Other Marketing Defendants Leapt at the Opioid Opportunity	90
E.	The Marketing Defendants' Multi-Pronged Scheme to Change Prescriber Habits and Public Perception and Increase Demand for Opioids.....	93
1.	The Marketing Defendants Promoted Multiple Falsehoods About Opioids	95
2.	The Marketing Defendants Disseminated Their Misleading Messages about Opioids Through Multiple Channels	145
i.	The Marketing Defendants Directed Front Groups to Deceptively Promote Opioid Use	145
ii.	The Marketing Defendants Paid Key Opinion Leaders to Deceptively Promote Opioid Use.....	160
iii.	The Marketing Defendants Disseminated Their Misrepresentations Through Continuing Medical Education Programs	171
i.	The Marketing Defendants Used "Branded" Advertising to Promote their Products to Doctors and Consumers.....	174
ii.	The Marketing Defendants Used "Unbranded" Advertising to Promote Opioid Use for Chronic Pain Without FDA Review	175
iii.	The Marketing Defendants Funded, Edited and Distributed Publications That Supported Their Misrepresentations	175
iv.	The Marketing Defendants Used Detailing to Directly Disseminate Their Misrepresentations to Prescribers	177
v.	Marketing Defendants Used Speakers' Bureaus and Programs to Spread Their Deceptive Messages.....	181
3.	The Marketing Defendants Targeted Vulnerable Populations.....	182
4.	The Marketing Defendants Had an Obligation to Educate Doctors to Prevent Future Harm	184
5.	The Marketing Defendants' Scheme Succeeded, Creating a Public Health Epidemic	184
i.	Marketing Defendants' dramatically expanded opioid prescribing and use.	184
ii.	Marketing Defendants' deception in expanding their market created and fueled the opioid epidemic.	187

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

F.	The Supply Chain Defendants and National Pharmacies Deliberately Disregarded Their Duties to Maintain Effective Controls Against Diversion.....	188
1.	ARCOS / DADS DATA	190
2.	As Registrants Under the Controlled Substances Act, Supply Chain Defendants and National Pharmacies Have a Duty to Maintain Effective Controls Against Diversion and Supply Chain Defendants Have a Duty to Detect, Report, and Halt Suspicious Orders.....	195
iii.	Federal Statutory Duty	196
iv.	Federal Regulatory Duty.....	198
v.	DEA Guidance	200
vi.	Duties pursuant to West Virginia Law.....	205
3.	Supply Chain Defendants and National Pharmacies Have a Duty to Apply their Specialized Knowledge of the Market to Prevent Diversion	208
4.	Supply Chain Defendants and National Pharmacies Were Aware of and Have Acknowledged Their Obligations to Prevent Diversion and to Report and Take Steps to Halt Suspicious Orders	214
5.	Defendants Kept Careful Track of Prescribing Data and Knew About Suspicious Orders and Prescribers	217
6.	Despite Repeated Admonitions, Supply Chain Defendants Continued to Violate their Legal Obligations and Failed to Act to Prevent Diversion.....	225
7.	Supply Chain Defendants and National Pharmacies Breached Their Legal Duties and Failed to Prevent Diversion.....	232
i.	AMERISOURCE BERGEN	233
ii.	CARDINAL HEALTH.....	239
iii.	McKESSON.....	253
iv.	CVS.....	263
v.	WALGREENS	269
vi.	H.D. SMITH	279
vii.	KROGER	282
viii.	RITE AID.....	284
ix.	WALMART	288
x.	MALLINCKRODT.....	291
xi.	ACTAVIS	298
xii.	PURDUE.....	302
xiii.	KVK TECH	304
xiv.	ENDO	306
xv.	JANSSEN	308
xvi.	CEPHALON	310
xvii.	AMNEAL	312
xviii.	NATIONAL PHARMACIES	313

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

G.	Defendants' Violations in Other Jurisdictions Further Exacerbated the Flood of Opioids into the City of Huntington and Cabell County.....	321
H.	Defendants Delayed a Response to the Opioid Crisis by Pretending to Cooperate with Law Enforcement	323
I.	Defendants Worked Together to Sustain their Market and Boost their Profits.....	326
1.	Defendants Worked Together to Inflate Quotas	326
2.	Defendants Worked Together to Shape State and Federal Policy	329
3.	Distributor Defendants Marketed Manufacturers' Opioid Products.....	335
J.	The PBM Defendants Further Exacerbated the Flood of Opioids into the Market.....	338
K.	Collectively, the Defendants' Actions have had a Devastating Effect on Plaintiffs' Communities	341
L.	Statute of Limitations are Tolled and Defendants Are Estopped From Asserting Statutes of Limitations as Defenses	356
1.	Continuing Conduct	356
2.	Equitable Estoppel and Fraudulent Concealment	356
II.	Facts Pertaining To Claims Under the Racketeer-Influenced and Corrupt Organizations (“RICO”) Act.....	359
A.	The Opioid Marketing Enterprise	359
1.	The Common Purpose and Scheme of the Opioid Marketing Enterprise	359
2.	The Conduct of the Opioid Marketing Enterprise violated Civil RICO	363
3.	The RICO Marketing Defendants Controlled and Paid Front Groups and KOLs to Promote and Maximize Opioid Use	367
B.	The Opioid Supply Chain Enterprise	371
C.	Facts Pertaining to Punitive Damages	412
1.	The Marketing Defendants Persisted in Their Fraudulent Scheme Despite Repeated Admonitions, Warnings, and Even Prosecutions	414
a.	FDA Warnings to Janssen Failed to Deter Janssen's Misleading Promotion of Duragesic	414
a.	Governmental Action, Including Large Monetary Fines, Failed to Stop Cephalon from Falsely Marketing Actiq for Off-Label Uses.....	415
b.	FDA Warnings Did Not Prevent Cephalon from Continuing False and Off-Label Marketing of Fentora	415
c.	A Guilty Plea and a Large Fine Did Not Deter Purdue from Continuing Its Fraudulent Marketing of OxyContin	416

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

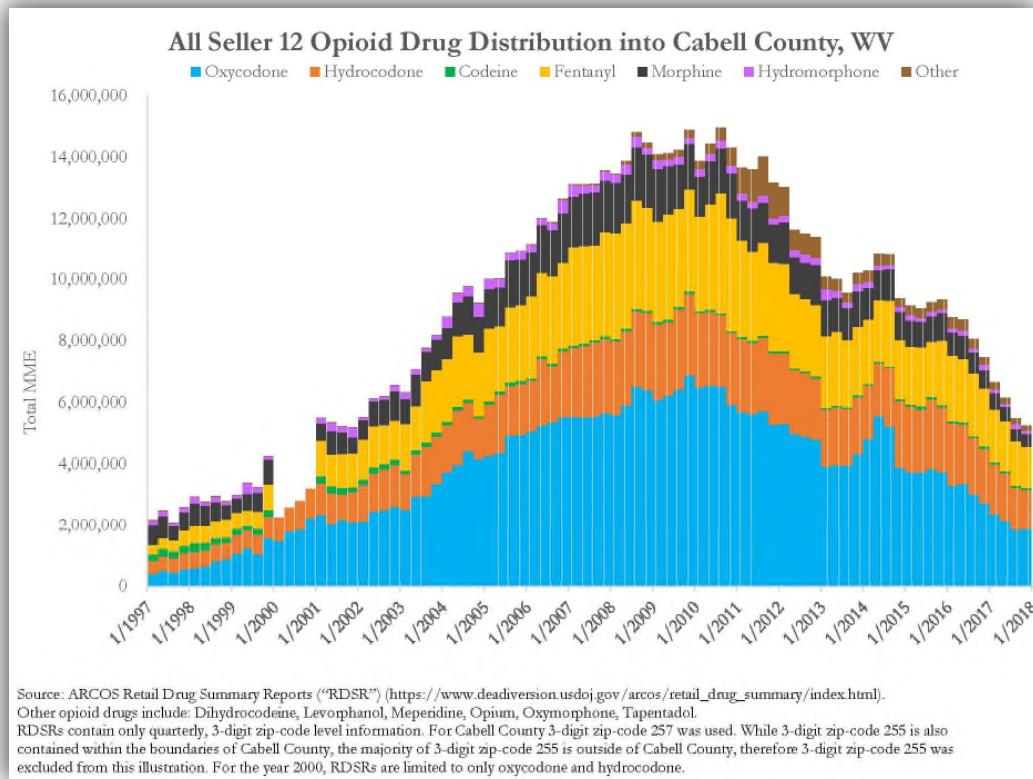
2. Repeated Admonishments and Fines Did Not Stop Defendants from Ignoring Their Obligations to Control the Supply Chain and Prevent Diversion	417
CLAIMS FOR RELIEF	423
FIRST CLAIM FOR RELIEF Common Law Public Nuisance	
(Against All Defendants)	423
SECOND CLAIM FOR RELIEF	433
Violation of RICO, 18 U.S.C. § 1961 <i>et seq.</i> – Opioid Marketing Enterprise (Against Defendants Purdue, Cephalon, Janssen, Endo, and Mallinckrodt (the “RICO Marketing Defendants”)).....	433
THIRD CLAIM FOR RELIEF Violation of RICO, 18 U.S.C. § 1961 <i>et seq.</i> – Opioid Supply Chain Enterprise (Against Defendants Purdue, Cephalon, Endo, Mallinckrodt, Actavis, McKesson, Cardinal Health, and AmerisourceBergen (the “RICO Supply Chain Defendants”)).....	444
FOURTH CLAIM FOR RELIEF Negligence (Against Supply Chain Defendants)	452
FIFTH CLAIM FOR RELIEF Violation of West Virginia Controlled Substances Act; W.Va. Code Section § 55-7-9 (Against Supply Chain Defendants)	461
SIXTH CLAIM FOR RELIEF Unjust Enrichment (Against Supply Chain Defendants, National Pharmacies, Purdue Officers and Directors, and PBMs)	463
SEVENTH CLAIM FOR RELIEF Civil Conspiracy (Against Supply Chain Defendants)	464
EIGHTH CLAIM FOR RELIEF Punitive Damages (Against All Defendants).....	466
PRAYER FOR RELIEF.....	467

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER**PRELIMINARY STATEMENT**

1. There is an immediate hazard to public health and safety in Cabell County and the City of Huntington, West Virginia arising out of an opioid epidemic.
2. One author described the crisis as follows:

One afternoon in August 2016, one call after another hit the 911 lines in Huntington – people overdosing in gas station bathrooms, passing out in the bath, collapsing outside the Burger King. Twenty-eight people overdosed over a period of four hours. . . . Overdoses in Huntington escalated to more than twelve hundred in 2016, nearly double the previous year. Paramedics reported going into homes to save a life and finding almost everything has been sold to pay for drugs or children sitting in the middle of the living room floor while their parents are passed out in the bedroom. One in ten babies born in Huntington is dependent on opioids.¹

3. A massive volume of oxycodone, hydrocodone, and other prescription opioids was sold into Cabell County, West Virginia and its county seat, the City of Huntington:

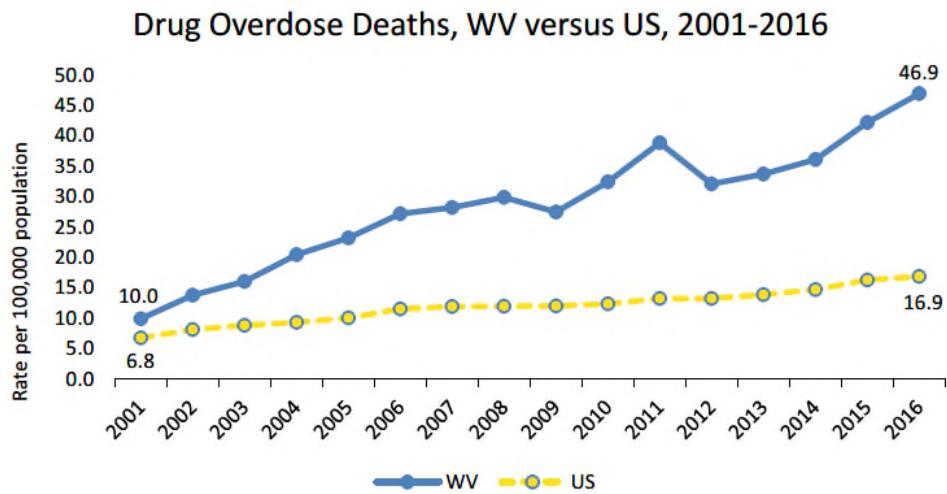


¹ Chris McGreal, *American Overdose: The Opioid Tragedy in Three Acts*, p. 289.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

4. Between 2006 and 2014, Manufacturers and Distributors of prescription opioids have showered the state of West Virginia with [REDACTED] hydrocodone and oxycodone pills.² The massive over-shipment amounts to [REDACTED] pain pills for every man, woman and child in the state of West Virginia.

5. As the volume of prescription opioids flooding into West Virginia increased, so, too, did the death toll.



Source: West Virginia Board of Pharmacy, *Prescription Opioid Problematic Prescribing Indicators County Report: Cabell County*, October 2017

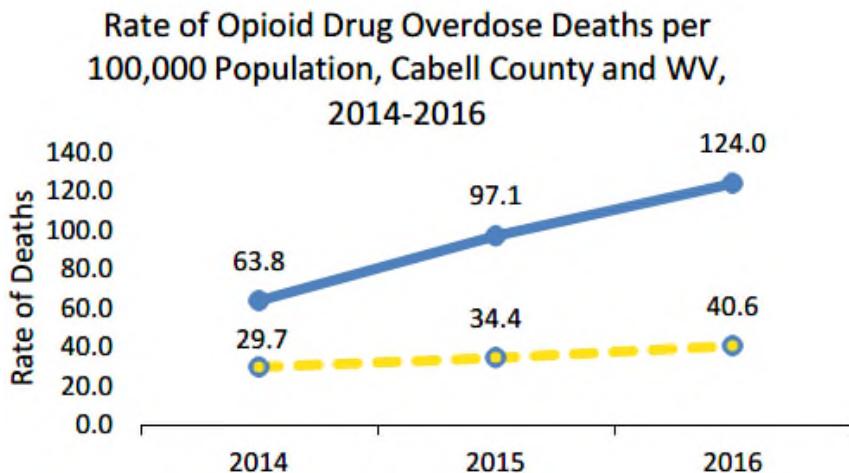
6. Nationally, from 1999 through 2016, more than 350,000 people in the U.S. died from an overdose involving opioids -- more than the number of Americans who died in the Vietnam War. Well over half of those deaths—over 200,000 people—involved opioids prescribed by doctors to treat pain. Such opioids include brand-name prescription medications like OxyContin, Opana ER, Vicodin, and Duragesic, as well as generics like oxycodone, hydrocodone, and fentanyl.

² See ARCOS Data produced in MDL 2804. Unless otherwise stated, distribution statistics throughout the Complaint are from this ARCOS Data.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

7. West Virginia has the highest age-adjusted rate of drug overdose deaths involving opioids in the nation. In 2017, there were 833 drug overdose deaths involving opioids in West Virginia—a rate of 49.6 deaths per 100,000 persons. This is the double the rate in 2010 and threefold higher than the national rate of 14.6 deaths per 100,000 persons.³ While the national rate of drug overdose deaths increased 149% from 2001 to 2016, West Virginia saw a 369% increase.

8. The rate of drug overdose deaths in Cabell County is even higher than the state average. In 2017, 183 people died of a drug overdose in Cabell County – more than in any other West Virginia county.



Source: West Virginia Board of Pharmacy, *Prescription Opioid Problematic Prescribing Indicators County Report: Cabell County*, October 2017

9. Most of the overdoses from non-prescription opioids are also directly related to prescription pills. Many opioid users, having become addicted to but no longer able to obtain prescription opioids, have turned to heroin. According to the American Society of Addiction Medicine, 80% of people who initiated heroin use in the past decade started with prescription painkillers. The CDC identified addiction to prescription pain medication as the strongest risk

³ National Institute on Drug Abuse (NIDA), West Virginia Opioid Summary, June 13, 2019, available at <https://www.drugabuse.gov/opioid-summaries-by-state/west-virginia-opioid-summary>.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

factor for heroin addiction. People who are addicted to prescription opioid painkillers are 40 times more likely to be addicted to heroin.

10. The City of Huntington and Cabell County are, by now, well-known for being situated at ground zero of the opioid epidemic sweeping the nation.

11. The opioid epidemic in Cabell County and City of Huntington continues to rage.⁴ To date, the epidemic in the City of Huntington and Cabell County has not been abated by actions to address the crisis at the local, state and federal levels.⁵ This civil action attempts to bring about a solution, by holding those accountable who so blatantly, repeatedly and unlawfully increased the demand for and sale of opioids and those who contributed to the gross oversupply of these drugs into Cabell County and the City of Huntington. The Cabell County Commission and the City of Huntington seek a reckoning to force corporate drug dealers to internalize the external costs of abating the opioid epidemic.

12. As the Southern District of West Virginia recognized in 2017, “[t]he heroin and opioid crisis is a cancer that has grown and metastasized in the body politic of the United States.”⁶ “West Virginia has the highest rate of fatal drug overdoses in the nation—and that rate continues to rise.”⁷ “The heroin and opioid crisis in our state implicates the general welfare in a preeminent way.”⁸ “The current heroin and opioid epidemic is carving a path of pain and suffering that cuts across race, socioeconomic status, and age and afflicts everyone in our community.”⁹ As Mayor

⁴ Scholl L, Seth P, Kariisa M, Wilson N, Baldwin G. Drug and Opioid-Involved Overdose Deaths — United States, 2013–2017. MMWR Morb Mortal Wkly Rep 2019;67:1419–1427.

⁵ See Barack Obama, President of the United States, Epidemic: Responding to America’s Prescription Drug Abuse Crisis (2011).

⁶ *United States v. Walker*, No. 2:17-CR-00010, 2017 WL 2766452, at *3 (S.D.W. Va. June 26, 2017)

⁷ *Id.* at *6.

⁸ *Id.* at *7.

⁹ *United States v. Wilmore*, 282 F. Supp. 3d 937, 948 (S.D.W. Va. 2017)

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

Steve Williams of Huntington described: “The epidemic of addiction is now so pervasive that our standard of living, our way of life and our children’s future is at stake.”¹⁰

13. This civil action is one of more than 1600 cases pending in MDL 2804, *In re: National Prescription Opiate Litigation*, in front of Judge Dan Aaron Polster in the United States District Court for the Northern District of Ohio, wherein governmental entities from across the United States of America seek redress against the parties who brought about the opioid epidemic by unlawfully marketing and distributing these drugs. Plaintiffs Cabell County Commission and the City of Huntington were selected as the second bellwether case in the MDL on December 31, 2018 (Dkt. No. 1218). Plaintiffs consent and accept the task of advancing the interests of MDL 2804 by filing this Joint Complaint and directing the Court’s attention to the unlawful conduct of Defendants charged with the non-delegable duty to maintain effective controls against diversion¹¹ and those wrongful conduct initiated and/or exacerbated the flood of opioids in West Virginia. Plaintiffs bring this civil action to eliminate the hazard to public health and safety, to abate the public nuisance caused by the opioid epidemic in the City and County and to compensate both for abatement measures undertaken or underway and damages sustained as a result of the opioid epidemic proximately caused by *Purdue Pharma L.P.*, *Purdue Pharma Inc.*, *The Purdue Frederick Company, Inc.*, *Rhodes Pharmaceuticals L.P.*, *Rhodes Technologies, Inc.*, *Richard S. Sackler, M.D.*, *Kathe A. Sackler*, *Jonathan D. Sackler*, *Mortimer D.A. Sackler*, *Ilene Sackler Lefcourt, Beverly Sackler*, *Theresa Sackler*, *David A. Sackler*, *Allergan Plc f/k/a Actavis plc f/k/a Allergan Inc.*, *Allergan Finance, LLC f/k/a Actavis Inc. f/k/a Watson Pharmaceuticals, Inc.*, *Allergan Sales, LLC*, *Allergan USA, Inc.*, *Watson Laboratories, Inc.*, *Warner Chilcott Company, LLC*, *Actavis*

¹⁰ Mayor Steve Williams, City of Huntington, Letter to the residents of Huntington and the Tri-State Region, Mayor’s Office of Drug Control Policy Strategic Plan, August 24, 2015.

¹¹ See 21 U.S.C. § 823 [1970]; *Masters Pharm., Inc. v. Drug Enf’t Admin.*, 861 F.3d 206 (D.C. Cir. 2017) (citing 21 CFR 1301.74(b) [1971]); 21 C.F.R. § 1301.71.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

Pharma, Inc. f/k/a Watson Pharma Inc., Actavis South Atlantic LLC, Actavis Elizabeth LLC, Actavis Mid Atlantic LLC, Actavis Totowa LLC, Actavis LLC, Actavis Kadian LLC, Actavis Laboratories UT, Inc., Actavis Laboratories FL, Inc., Johnson & Johnson, Janssen Pharmaceuticals, Inc., Noramco, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc. n/k/a Janssen Pharmaceuticals, Inc., Janssen Pharmaceutica, Inc. n/k/a Janssen Pharmaceuticals, Inc., Endo Health Solutions Inc., Endo Pharmaceuticals, Inc., Par Pharmaceutical, Inc., Teva Pharmaceuticals USA, Inc., Par Pharmaceutical Companies, Inc. f/k/a Par Pharmaceutical Holdings, Inc., Cephalon, Inc., Teva Pharmaceutical Industries, Ltd., Mallinckrodt Plc, Mallinckrodt LLC, Specgx LLC, Kvk-Tech, Inc., Amneal Pharmaceuticals LLC, Amneal Pharmaceuticals, Inc., Amneal Pharmaceuticals of New York LLC, Impax Laboratories, LLC, AmerisourceBergen Drug Corporation, Cardinal Health, Inc., McKesson Corporation, CVS Health Corporation, CVS Pharmacy, Inc., CVS Indiana L.L.C., CVS Rx Services, Inc., CVS Tennessee Distribution, L.L.C., West Virginia CVS Pharmacy, LLC, Rite Aid Corporation, Rite Aid Of Maryland, Inc. d/b/a Rite Aid Mid-Atlantic Customer Supper Center, Inc., Rite Aid Of West Virginia, Inc., Walgreens Boots Alliance, Inc., Walgreen Co., Walgreen Eastern Co. Inc., H. D. Smith Wholesale Drug Co., Kroger Limited Partnership I, Kroger Limited Partnership II, Walmart Inc., Wal-Mart Stores East, L.P d/b/a Walmart Pharmacy Warehouse #46, Wal-Mart Pharmacy Warehouse, Wal-Mart Pharmacy Warehouse #45, Express Scripts Holding Company, Express Scripts, Inc., Caremark Rx, LLC, Optum, Inc., OptumRx Inc., and Tasmanian Alkaloids Pty. Ltd.¹²

¹² Modifications to the named Defendants from the Second Amended Complaints to the Third Amended and Joint Complaint are as follows:

- The following are *newly added* Defendants which neither Cabell County nor City of Huntington named in their respective Second Amended Complaints:
- Rhodes Pharmaceuticals L.P., Rhodes Technologies, Inc., Richard S. Sackler, M.D., Kathe A. Sackler, Jonathan D. Sackler, Mortimer D.A. Sackler, Ilene Sackler Lefcourt, Beverly Sackler, Theresa Sackler, David A. Sackler, Allergan Sales, LLC, Allergan USA, Inc. Warner Chilcott Company, LLC, Actavis

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

14. The City of Huntington and Cabell County are, by now, well-known for being situated at ground zero of the opioid epidemic sweeping the nation

15. This epidemic has been fueled and sustained by those involved in the supply chain of opioids, including manufacturers, distributors, pharmacies, and pharmacy benefit managers (together, “Defendants”), who (1) engineered a dramatic shift in how and when opioids are prescribed by the medical community and used by patients and (2) failed to maintain effective controls over the distribution of prescription opioids, by – among other things – selling and distributing far greater quantities of prescription opioids than they know could be necessary for legitimate medical uses, while failing to report, and to take steps to halt suspicious orders when they were identified.

South Atlantic LLC, Actavis Elizabeth LLC, Actavis Mid Atlantic LLC, Actavis Totowa LLC, Actavis Kadian LLC, Actavis Laboratories UT, Inc., Actavis Laboratories FL, Inc., , KVK-Tech, Inc., Amneal Pharmaceuticals LLC, Amneal Pharmaceuticals, Inc., Amneal Pharmaceuticals of New York LLC, Impax Laboratories, LLC, CVS Pharmacy, Inc., CVS Indiana L.L.C., CVS Rx Services, Inc., CVS Tennessee Distribution, L.L.C., West Virginia CVS Pharmacy, LLC, Rite Aid Of West Virginia, Inc., Walgreen Co., Express Scripts Holding Company, Express Scripts, Inc., Caremark Rx, LLC, CVS Health Corporation, Optum, Inc., OptumRx Inc., Tasmanian Alkaloids Pty. Ltd.

- Subsequent to the filing of its Second Amended Complaint, on July 6, 2018, Plaintiff Cabell County dismissed Rite Aid Corporation without prejudice.
- Subsequent to the filing of its Second Amended Complaint, on July 16, 2018, Plaintiff Cabell County:
 - i. Dismissed CVS Health Corporation without prejudice
 - ii. Dismissed Walgreens Boot Alliance, Inc., without prejudice
 - iii. Substituted parties CVS Tennessee Distribution, LLC, CVS Indiana LLC, and CVS RX Services, Inc.
- CVS Indiana LLC was previously named in the City of Huntington’s Second Amended Complaint.
- The following were named as Defendants in the Second Amended Complaint, but are no longer named in the Third Amended Complaint: Insys.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

16. As a direct and foreseeable result of Defendants' conduct, the nation and the Plaintiffs are now swept up in what the Centers for Disease Control ("CDC") has called a "public health epidemic" and what the U.S. Surgeon General has deemed an "urgent health crisis."¹³

17. The increased volume of opioid prescribing, correlates directly to skyrocketing addiction, overdose, and death; black markets for diverted prescription opioids; and a concomitant rise in heroin and fentanyl abuse by individuals who could no longer legally acquire—or simply could not afford—prescription opioids. According to the National Bureau of Economic Research, 85% of opioid-related deaths are due to increased prescribing of opioids.¹⁴ Nationally, the number of deaths due to drug overdoses rose from 16,849 in 1999 to 70,237 in 2017.¹⁵ The United States Center for Disease Control ("CDC") estimates that more than two-thirds of the drug overdose deaths in 2017 were due to opioids.¹⁶ The number of deaths associated with this crisis is expected to be even higher in 2018.

18. The Defendants' actions, motivated by financial gain without regard to the welfare of Cabell County, the City of Huntington, and their residents, have caused substantial damages, including, but not limited to, increased expenses of drug abuse treatment programs, prevention and training costs (for law enforcement, hospitals and schools), costs of the drug Naloxone as well as education, training and use, youth development community programs, medical care and hospitalizations, increased costs of law enforcement, increased costs of prosecutions and most significantly increased costs of incarcerations.

¹³ CDC, *Examining the Growing Problems of Prescription Drug and Heroin Abuse*, Apr. 29, 2014, available at <http://www.cdc.gov/washington/testimony/2014/t20140429.htm>; Vivek H. Murthy, *Letter from the Surgeon General*, Aug. 2016, available at <http://turnthetiderx.org>.

¹⁴ Christopher J. Ruhm, National Bureau of Economic Research Paper, *Deaths of Despair or Drug Problems?*, Jan. 2018.

¹⁵ *Id.*

¹⁶ <https://www.cdc.gov/drugoverdose/>

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

19. Defendants' conduct in promoting and facilitating opioid use and thereby causing addiction, abuse, overdose and death has had severe and far-reaching public health, social services, and criminal justice consequences, including the fueling of addiction and overdose from illicit drugs such as heroin. Plaintiffs have borne these costs for the benefit of their community, as have other local governments. These necessary and costly responses to the opioid crisis include those associated with handling of emergency responses to overdoses, providing addiction treatment, handling opioid-related investigations, arrests, adjudications, and incarceration, treating opioid-addicted newborns in neonatal intensive care units, burying the dead, and placing thousands of children in foster care placements. The epidemic has led to a public health crisis with increasing numbers of Hepatitis B, Hepatitis C and HIV. There has also been a startling increase in infants born with Neonatal Abstinence Syndrome (NAS).

20. According to the CDC, the number of babies born with NAS increased by more than 300 percent between 1999 and 2013. In the City of Huntington and Cabell County, however, the problem is exponentially worse. The CDC reports this area as having the highest rate of NAS in the nation – nearly 33 cases of NAS per 1,000 hospital births.¹⁷

21. The burdens imposed on Plaintiffs are not the normal or typical burdens of government programs and services. Rather, these are extraordinary costs and losses that are related directly to Defendants' illegal actions. The Defendants' conduct has created a public nuisance and a blight. Governmental entities, and the services they provide their citizens, have been strained to the breaking point by this public health crisis.

¹⁷ Loudin S, Werthammer J, Prunty L, Murray S, Shapiro JI, Davies TH. A management strategy that reduces NICU admissions and decreases charges from the front line of the neonatal abstinence syndrome epidemic. *J Perinatol.* 2017;37(10):1108–1111. doi:10.1038/jp.2017.101

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

22. The Plaintiffs have been severely damaged by Defendants' collective actions. The Defendants have illegally and tortiously profited from the prescription drug abuse problems knowingly dumping opioids into the City of Huntington and Cabell County. Further, many users of prescription opioids, which at the molecular level and in their effect, closely resemble heroin, have turned to heroin after becoming addicted to, but no longer able to obtain, prescription opioids. The devastation caused by the Defendants goes beyond and cannot be adequately conveyed by recounting the economic damage; City of Huntington and Cabell County families have lost children, parents and grandparents. This epidemic of opioid abuse caused by the Defendants has taken and destroyed the lives of many residents of the City of Huntington and Cabell County.

23. Defendants have not changed their ways or corrected their past misconduct but instead are continuing to fuel the crisis.

24. Within the next hour, six Americans will die from opioid overdoses; two babies will be born addicted to opioids and begin to go through withdrawal; and drug manufacturers will earn over \$2.7 million from the sale of opioids.

25. Plaintiffs bring this suit to bring the devastating march of this epidemic to a halt and to hold Defendants responsible for the crisis they caused.

PARTIES

I. PLAINTIFFS

26. Plaintiff the **CITY OF HUNTINGTON, WEST VIRGINIA** ("City of Huntington") is a public corporation which may sue and plead in its own name.¹⁸ Plaintiff is a "political subdivision" and is neither an agency nor an agent of the State of West Virginia.¹⁹

¹⁸ W. Va. Code § 7-1-1(a) [2008].

¹⁹ W. Va. Code § 29-12A-3(c) [1986]; W. Va. Code § 14-2-3 [1967]; *Kucera v. City of Wheeling*, 153 W. Va. 531, 170 S.E.2d 217 (1969).

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

27. The City of Huntington is the county seat of Cabell County, West Virginia,²⁰ and has a population of **49,138 people**, according to the 2010 U.S. Census report.

28. The City of Huntington is also the largest city in the Huntington-Ashland metro area.

29. Plaintiff **CABELL COUNTY COMMISSION** ("Cabell County), is a West Virginia political subdivision²¹ which may sue and plead in its own name²² and has standing²³ to take "appropriate and necessary actions for the elimination of hazards to public health and safety and to abate or cause to be abated anything which the commission determines to be a public nuisance."²⁴

30. Cabell County has a population of **96,319 people** according to the 2010 U.S. Census report.

31. From 2006 through 2014, **more than [REDACTED] doses of hydrocodone and oxycodone** were sold in Cabell County, West Virginia.²⁵

32. Cabell County, West Virginia is one of the three "core counties" in the Huntington-Ashland-Ironton Metropolitan Statistical Region, as defined by the United States Office of Management and Budget, along with Lawrence County, Ohio and Boyd County, Kentucky.

²⁰ A small portion of the City of Huntington is also located within Wayne County, West Virginia.

²¹ The CABELL COUNTY COMMISSION is neither an agency nor an agent of the State of West Virginia. W. Va. Code § 29-12A-3(c) [1986]; W. Va. Code § 14-2-3 [1967]; *Kucera v. City of Wheeling*, 153 W. Va. 531, 170 S.E.2d 217 (1969). Nor does the West Virginia Attorney General have authority to release the claims of the CABELL COUNTY COMMISSION.

²² W. Va. Code § 7-1-1(a) [2008]

²³ A county commission only has powers expressly conferred by the West Virginia Constitution and our State Legislature, or powers reasonably and necessarily implied for the exercise of those expressed powers. *Berkeley Cty. Comm'n v. Shiley*, 170 W. Va. 684, 685–86, 295 S.E.2d 924, 926 (1982) (citing *State ex rel. County Court of Cabell County v. Arthur*, 150 W.Va. 293, 145 S.E.2d 34, Syl. Pt. 1 [1965]). The CABELL COUNTY COMMISSION is vested with the power of all superintendence and administration of the internal police and fiscal affairs of Cabell County. W. Va. Code § 7-1-3 [1999].

²⁴ W. Va. Code § 7-1-3kk [2002].

²⁵ See ARCOS Data produced in MDL 2804.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

33. Opioids sold within all three counties (Lawrence County, Ohio; Boyd County, Kentucky; and Cabell County, West Virginia) have a significant, known impact on Cabell County, West Virginia and the City of Huntington.

34. *More than [REDACTED] doses of hydrocodone and oxycodone* were sold into Lawrence County, Ohio; Boyd County, Kentucky; and Cabell County, West Virginia from 2006-2014.²⁶

35. Cabell County is located within the convergence point for the West Virginia, Kentucky, and Ohio Tri-State area.

36. Opioids sold within all three states (West Virginia, Kentucky, and Ohio) have a significant, known impact on the City of Huntington and Cabell County, West Virginia.

37. The distribution, sale, and diversion of opioids into West Virginia (“the State”) and into the City of Huntington and into Cabell County and surrounding areas (collectively, “**Plaintiffs’ Community**”), created the foreseeable opioid crisis and opioid public nuisance for which City of Huntington and Cabell County Commission (collectively, “**Plaintiffs**”) here seek relief.

38. Further, excessive and suspicious distributions and sales of opioids into Florida were known by Defendants to travel to the Tri-States, including to West Virginia and the Plaintiffs’ Community, and further contributed to the foreseeable opioid crisis and public nuisance. Plaintiffs have declared, *inter alia*, that opioid abuse, addiction, morbidity, and mortality has created a serious public health and safety crisis, and is a public nuisance, and that the diversion of legally produced controlled substances into the illicit market causes or contributes to this public nuisance.

²⁶ See ARCOS Data produced in MDL 2804.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

39. Plaintiffs directly and foreseeably sustained all economic damages alleged herein. Defendants' conduct has exacted a financial burden for which the Plaintiffs seek relief. These damages have been suffered, and continue to be suffered directly, by the Plaintiffs.

40. Plaintiffs also seek the means to abate the epidemic created by Defendants' wrongful and/or unlawful conduct.

41. Plaintiffs have standing to recover damages incurred as a result of Defendants' actions and omissions. Plaintiffs have standing to bring all claims pled herein, including, *inter alia*, to bring claims under the federal RICO statute, pursuant to 18 U.S.C. § 1961(3) ("persons" include entities which can hold legal title to property) and 18 U.S.C. § 1964 ("persons" have standing).

II. DEFENDANTS

A. Manufacturer Defendants

42. At all relevant times, the Manufacturer Defendants, each of whom is defined below, have packaged, distributed, supplied, sold, placed into the stream of commerce, labeled, described, marketed, advertised, promoted or purported to inform prescribers and users regarding the benefits and risks associated with the use of the prescription opioid drugs. The Manufacturer Defendants, at all times, have manufactured and sold prescription opioids without fulfilling their legal duty to prevent diversion and detect, report, and not ship suspicious orders. For ease of reference, the Manufacturer Defendants are also referred to as "Marketing Defendants" and Distributors as "Distributor Defendants," though both manufacturers and distributors engaged in the marketing and distribution of opioids, and had, and failed to meet, the responsibilities of both.

1. Purdue Companies

43. Defendant **PURDUE PHARMA L.P.** ("PPL") is a limited partnership organized under the laws of Delaware with its principal place of business in Stamford, Connecticut.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

44. Defendant **PURDUE PHARMA INC.** (“PPI”) is a New York corporation with its principal place of business in Stamford, Connecticut.

45. Defendant **THE PURDUE FREDERICK COMPANY, INC.** (“PFC”) is a New York corporation with its principal place of business in Stamford, Connecticut.

46. Defendant **RHODES PHARMACEUTICALS L.P.** is a limited partnership organized under the laws of Delaware with its principal place of business in Coventry, Rhode Island. Rhodes Pharmaceuticals L.P. has one general partner, Rhodes Pharmaceuticals, Inc.; and one limited partner, Coventry Technologies L.P., which holds Rhodes Pharmaceuticals, L.P.’s shares. Coventry Technologies L.P. is a Delaware limited partnership with its principal place of business in Stamford, Connecticut. Its general partner is Purdue Pharma Inc. **Rhodes Technologies Inc.** is a corporation organized under the laws of Delaware with its principal place of business in Coventry, Rhode Island. **Rhodes Technologies** is a Delaware general partnership with its principal place of business in Coventry, Rhode Island. Rhodes Technologies Inc. is the general partner of Rhodes Technologies and is a subsidiary of Purdue Pharma, L.P. (Rhodes Technologies and Rhodes Pharmaceuticals are collectively referred to as “Rhodes”). Rhodes manufactures and distributes generic opioids, including authorized generic versions of OxyContin and Butrans. Rhodes Technologies also manufacturers the active pharmaceutical ingredient in drugs including Purdue’s OxyContin.²⁷ Among the drug products manufactured by Rhodes is buprenorphine, a drug used to treat opioid dependence.

47. Although it is registered as a separate corporate entity than Purdue Pharma L.P., Purdue Pharma, Inc., and The Purdue Frederick Company Inc. (collectively, “Purdue”), a former senior manager at Purdue described Rhodes Pharmaceuticals, L.P., as “set up as a ‘landing pad’

²⁷ At various times, Defendant Mallinckrodt also supplied Purdue with oxycodone.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

for the Sackler family in 2007, to prepare for the possibility that they would need to start afresh following the crisis then engulfing OxyContin.” Further, reporting by the *Financial Times* revealed that a 2017 manual showed that Rhodes and Purdue used the same employee handbook, and employees reported that “little distinction is made internally between the two companies.”²⁸ Together, Rhodes and Purdue accounted for 14.4 million opioid prescriptions in the United States in 2016.²⁹

48. PPL, PPI, PFC, Rhodes and their DEA registrant subsidiaries and affiliates (collectively, “**Purdue Companies**”) are engaged in the manufacture, promotion, distribution, and sale of opioids nationally and in the City of Huntington, including the following:

Product Name	Chemical Name	Schedule ³⁰
OxyContin	Oxycodone hydrochloride, extended release	Schedule II
MS Contin	Morphine sulfate, extended release	Schedule II
Dilaudid	Hydromorphone hydrochloride	Schedule II
Dilaudid-HP	Hydromorphone hydrochloride	Schedule II
Butrans	Buprenorphine	Schedule III
Hysingla ER	Hydrocodone bitrate	Schedule II
Targiniq ER	Oxycodone hydrochloride and naloxone hydrochloride	Schedule II

49. Purdue made thousands of payments to physicians nationwide ostensibly for activities including participating on speakers’ bureaus, providing consulting services, assisting in

²⁸ David Crow, *How Purdue’s ‘one-two’ punch fueled the market for opioids*, Financial Times, (Sept. 9, 2018), <https://www.ft.com/content/8e64ec9c-b133-11e8-8d14-6f049d06439c>.

²⁹ *Id.*

³⁰ Since passage of the Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C. § 801 *et seq.* (“CSA” or “Controlled Substances Act”), opioids have been regulated as controlled substances. As controlled substances, they are categorized in five schedules, ranked in order of their potential for abuse, with Schedule I being the most dangerous. The CSA imposes a hierarchy of restrictions on prescribing and dispensing drugs based on their medicinal value, likelihood of addiction or abuse, and safety. Opioids generally had been categorized as Schedule II or Schedule III drugs; hydrocodone and tapentadol were recently reclassified from Schedule III to Schedule II. Schedule II drugs have a high potential for abuse, and may lead to severe psychological or physical dependence. Schedule III drugs are deemed to have a lower potential for abuse, but their abuse still may lead to moderate or low physical dependence or high psychological dependence.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

post-marketing safety surveillance and other services, but in fact to deceptively promote and maximize the use of opioids.

50. OxyContin is Purdue's largest-selling opioid. Since 2009, Purdue's national annual sales of OxyContin have fluctuated between \$2.47 billion and \$3.1 billion, up four-fold from 2006 sales of \$800 million. OxyContin constitutes roughly 30% of the entire market for analgesic drugs (*i.e.*, painkillers). Sales of OxyContin (launched in 1996) went from a mere \$49 million in its first full year on the market to \$1.6 billion in 2002.

51. In 2007, Purdue settled criminal and civil charges against it for misbranding OxyContin and agreed to pay the United States \$635 million—at the time, one of the largest settlements with a drug company for marketing misconduct. None of this stopped Purdue. In fact, Purdue continued to create the false perception that opioids were safe and effective for long term use, even after being caught, by using unbranded marketing methods to circumvent the system. In short, Purdue paid the fine when caught and then continued business as usual, deceptively marketing and selling billions of dollars of opioids each year.

2. Purdue Directors and Officers

52. Defendant **RICHARD S. SACKLER, M.D.**, is a natural person residing in Travis County, Texas. He has served as a member of the Board of Directors of Purdue and Purdue-related entities since the 1990s. Richard Sackler was President of Purdue Pharma from 1999 to 2003 and Co-Chairman in 2003 through 2014. Upon information and belief, Sackler joined Purdue in 1971 as an assistant to his father, Dr. Raymond Sackler who was then President of Purdue. He served as head of Purdue's Marketing and Research & Development Departments. From 1995-2003, Defendant Richard Sackler oversaw the launch of OxyContin. Richard Sackler, upon information and belief, has long been the beneficiary of an ownership interest in Purdue and Rhodes, and continues to hold such an ownership interest. Through his decisions and directives, Richard

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

Sackler knowingly caused and approved the promotion and sales of Purdue and Rhodes opioids. Richard Sackler is the listed inventor on a number of patents assigned to Purdue or Rhodes, including U.S. Patent 9,3861,628, *Buprenorphine-Wafer for Drug Substitution Therapy* (January 9, 2018), a patent issued, inter alia, to Sackler and assigned by Sackler and his co-inventors to Rhodes covering a drug for “drug substitution therapy in drug-dependent human subjects.” In other words, having played no small part in causing the opioid epidemic, Richard Sackler, through his companies, is poised to profit off of its abatement.

53. Defendant **KATHE A. SACKLER** is a natural person residing in Fairfield County, Connecticut. Kathe Sackler began serving as Senior Vice President of Purdue by 2000. She resigned from her position in or about 2003. She has served as a member of the Board of Directors of Purdue and Purdue-related entities and on various Board committees since the 1990s and was instrumental in Purdue’s “Project Tango.”

54. Defendant **JONATHAN D. SACKLER** is a natural person residing in Fairfield County, Connecticut. Jonathan Sackler served as Senior Vice President of Purdue by 2000, until stepping down in 2003. He has served as a member of the Board of Directors of Purdue and Purdue-related entities since the 1990s.

55. Defendant **MORTIMER D.A. SACKLER** is a natural person residing in New York County, New York. He has served as a member of the Board of Directors of Purdue and Purdue-related entities since the 1990s.

56. Defendant **ILENE SACKLER LEFCOURT** is a natural person residing in New York County, New York. She has served as a member of the Board of Directors of Purdue and Purdue-related entities since the 1990s.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

57. Defendant **BEVERLY SACKLER** is a natural person residing in Fairfield County, Connecticut. She has served as a member of the Board of Directors of Purdue and Purdue-related entities since the 1990s.

58. Defendant **THERESA SACKLER** is a natural person residing in New York County, New York. She has served as a member of the Board of Directors of Purdue and Purdue-related entities since the 1990s.

59. Defendant **DAVID A. SACKLER** is a natural person residing in New York County, New York. He has served as a member of the Board of Directors of Purdue and Purdue-related entities since 2012.

60. Collectively, Defendants Richard, Kathe, Jonathan, Mortimer D.A., Ilene, Beverly, Theresa and David Sackler are referred to as the “**Sackler Family**” or the “**Sackler Defendants**. Together, the Sackler Defendants, upon information and belief, were not only aware of, but approved and exercised control over Purdue’s deceptive marketing.

61. For example, in a deposition taken for prior litigation, a Purdue legal secretary named Maureen Sara testified that in late 1999, she sent a memorandum to the Sacklers, including Richard Sackler, about what she had learned on the internet about “crushing the tablets [of OxyContin], taking the coating off, cooking it up. Shooting or snorting it.”

62. According to Barry Meier’s book Pain Killer, in early 2001, Purdue met with the DEA, which was starting to raise alarms over OxyContin overdoses. Defendant Sackler participated in this meeting and defended OxyContin as an extremely good drug. According to the book, the head of the DEA’s Office of Diversion Control leaned across to Defendant Sackler and stated: “People are dying. Do you understand that?” Evidently Richard Sackler either did not understand or care, for Purdue did nothing to rein in Purdue’s misleading promotion of OxyContin.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

And, internally, Richard Sackler chose to stigmatize and blame those who became addicted or began to abuse opioids. In February of 2001, he wrote that: “we have to hammer on the abusers in every way possible. They are the culprits and the problem. They are reckless criminals.”

63. Federal prosecutors came to suspect, however, that Purdue and certain of its executives were the criminals. In 2003, while a criminal investigation into Purdue and three other executives was underway, the Sackler Defendants all quietly resigned from their management positions. Nevertheless, the Sackler Defendants, upon information and belief, remained actively involved in Purdue’s affairs and would also have been aware of deceptive marketing in their capacity as a board members at all relevant times. This involvement is detailed in internal company documents obtained by the Massachusetts Attorney General, parts of which were made public in *Commonwealth of Mass. v. Purdue Pharma L.P., et al.*, C.A. No. 1884-cv-01808 (BLS2), First Amended Complaint, Complete Unredacted Corrected Version for the Public File Submitted According to Court Order January 31, 2019 (Mass. Super. Ct. Jan. 31, 2019) (hereinafter, the “MA AG Complaint”). For example, according to the MA AG Complaint, internal documents show that the Sackler Defendants contemplated selling Purdue after its criminal plea in 2007 and other strategies to allow them to “distribute more free cash flow” to themselves.”

64. As another example, Purdue’s Board, while the Sackler Defendants were members, voted to approve a criminal guilty plea by their company, including an Agreed Statement Of Facts admitting, in 2007, that, for more than six years, supervisors and employees intentionally deceived doctors about OxyContin: “Beginning on or about December 12, 1995, and continuing until on or about June 30, 2000, Purdue supervisors and employees, with the intent to defraud or mislead, marketed and promoted OxyContin as less addictive, less subject to abuse and diversion, and less likely to cause tolerance and withdrawal than other pain medications.” Purdue’s Board, while the

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

Sackler Defendants were members, also voted to enter a Corporate Integrity Agreement with the United States. The Sackler Defendants each certified in writing to the U.S. government that he or she had read and understood the rules under that Agreement, including requirements to ensure that Purdue did not deceive doctors and patients again and to report any deception.

65. Yet, even after their company pled guilty to criminal charges, the Sackler Defendants still failed to follow the rules. For example, the Sacklers received reports that Purdue continued to mail out thousands of deceptive marketing materials in the first half of 2007 alone, with the single most-distributed material being volume #1 of Purdue’s “Focused and Customized Education Topic Selections in Pain Management” (FACETS), which falsely claimed that physical dependence on opioids is not dangerous and instead improves patients’ “quality of life.” Internal documents illustrate the detailed information provided the Sackler Defendants concerning, for example, the hiring of sales representatives, the reports of concern the company received, and the “Region Zero” prescribers identified, internally, as suspicious.

66. From the time Purdue first developed OxyContin, the Sackler Defendants were focused on sales. Richard Sackler had grand ambitions for Purdue; according to a long-time Purdue sales representative, “Richard really wanted Purdue to be big—I mean really big.” At the OxyContin launch party, Richard Sackler spoke as the Senior Vice President responsible for sales, and asking his listeners to envision natural disasters, went on to say: “the launch of OxyContin Tablets will be followed by a blizzard of prescriptions that will bury the competition. The prescription blizzard will be so deep, dense, and white....” When sales appeared to slow, or did not meet their expectations in later years, the Sackler Defendants expressed concern and looked for way to increase their sales (and by extension, the volume and dose of opioids being prescribed and used). For example, internal correspondence from 2011 reveals Jonathan Sackler writing to

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

John Stewart concerning sales that “this is starting to look ugly” and they needed to “talk,” after which Stewart and the sales team planned a response and to set up a meeting with Jonathan. Similarly, in internal e-mails concerning OxyContin prescriptions, in 2008, Kathe asked for information on “pressures” and “quantification of their negative impact on projected sales.” In 2012, Jonathan Sackler pressed Sales VP Russell Gasdia for periodic updates on sales. Richard Sackler was so deeply involved he even planned to go into the field with a sales representative. So intrusive was his involvement that an internal e-mail about his behavior reads: “Anything you can do to reduce the direct contact of Richard into the organization is appreciated.” During a deposition this past March, Richard Sackler was presented with numerous emails showing how often he asked staff for sales data. Yet, when asked if he ever requested data on OxyContin abuse or overdose rates, he responded “I don’t recall that.”³¹

67. This detailed attention and care given sales and profits contrasted sharply, as explained above, with the approach to addressing addiction, abuse, and diversion. For example, when Butrans sales were perceived as too low, internal documents described in the reveal that Richard Sackler wrote: “This is bad.” By contrast, when informed of 59 deaths from OxyContin in a single state, Richard Sackler wrote: “This is not too bad” and further explained that: “It could have been far worse.”

68. Kathe Sackler did pay close attention to opioid addiction, for profit, as part of a secret “Project Tango” which considered expanding Purdue’s business into addiction treatment. In connection with “Project Tango,” internal documents received by Kathe Sackler stated that “Pain treatment and addiction are naturally linked.” A confidential presentation made as part of

³¹ Sara Randazzo, *In Newly Released Deposition, OxyContin Owner Defends Response to Reports of Abuse*, The Wallstreet Journal, May 25, 2019

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

Project Tango highlighted, for example, the “[l]arge unmet need for vulnerable, underserved and stigmatized patient population.” Yet, Purdue continued to press its sales tactics.

69. According to internal documents, from the 2007 criminal convictions until 2018 alone, the Board, with the Sackler Defendants as members, voted to pay to out more than four billion dollars that would go to the Sackler family. Meanwhile, media reports describe Purdue as considering a bankruptcy filing. In the wake of the 2007 guilty plea and Corporate Integrity Agreement, a 2007 settlement with state attorneys general, and more recent lawsuits by state and local governments, as well as other plaintiffs, the Sackler Defendants should, upon information and belief, have anticipated the liability Purdue faced at the time they voted to take money out of the company.

3. Actavis Entities

70. Defendant **ALLERGAN PLC** (f/k/a Actavis plc, f/k/a Allergan, Inc.) is a public limited company incorporated in Ireland with its principal place of business in Dublin, Ireland, and its administrative headquarters and all executive officers located in Madison, New Jersey. In October 2012, the Actavis Group was acquired by Watson Pharmaceuticals, Inc., and the combined company changed its name to Actavis, Inc. as of January 2013, and then to Actavis plc in October 2013. In October 2013, Actavis plc (n/k/a Allergan plc) acquired Warner Chilcott plc pursuant to a transaction agreement dated May 19, 2013. Actavis plc (n/k/a Allergan plc) was established to facilitate the business combination between Actavis, Inc. (n/k/a Allergan Finance, LLC) and Warner Chilcott plc. Following the consummation of the October 1, 2013 acquisition, Actavis, Inc. (n/k/a Allergan Finance, LLC Inc.) and Warner Chilcott plc became wholly-owned subsidiaries of Actavis plc (n/k/a Allergan plc). Pursuant to the transaction, each of Actavis, Inc.’s common shares was converted into one Actavis plc share. Further, Actavis plc (n/k/a Allergan plc)

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

was the “successor issuer” to Actavis, Inc. and Warner Chilcott. Actavis plc acquired Allergan, Inc. in March 2015, and the combined company thereafter changed its name to Allergan plc.

71. The transaction that created Actavis plc converted each share of Actavis Inc.’s Class A common shares into one Actavis plc Ordinary Share. See City of Chicago v. Purdue Pharma L.P., et al. (N.D. Ill. 2015), No. 14-4361, 2015 WL 2208423, at *7. Actavis Inc. and Actavis plc had the same corporate headquarters both before and after the merger; Actavis plc had the same website as Actavis Inc.; and, Actavis plc maintained all of Actavis Inc.’s officers in the same positions. See id. Actavis plc’s SEC filings explained that “references throughout to ‘we,’ ‘our,’ ‘us,’ the ‘Company’ or ‘Actavis’ refer interchangeably to Watson Pharmaceuticals, Inc., Actavis, Inc., and Actavis plc depending on the date.” See City of Chicago v. Purdue Pharma L.P., et al. (N.D. Ill. 2015), No. 14-4361, 2015 WL 2208423, at *7.

72. Defendant **ALLERGAN FINANCE, LLC** (f/k/a Actavis, Inc., f/k/a Watson Pharmaceuticals, Inc.) is a limited liability company incorporated in Nevada and headquartered in Madison, New Jersey. Allergan Finance, LLC is a wholly-owned subsidiary of defendant Allergan plc. In 2008, Actavis, Inc. (n/k/a Allergan Finance, LLC), acquired the opioid Kadian through its subsidiary, Actavis Elizabeth LLC, which had been the contract manufacturer of Kadian since 2005. Since 2008, Kadian’s label has identified the following entities as the manufacturer or distributor of Kadian: Actavis Elizabeth LLC, Actavis Kadian LLC, Actavis Pharma, Inc., and Allergan USA, Inc. Currently, Allergan USA, Inc. is contracted with UPS SCS, Inc. to distribute Kadian on its behalf.

73. Defendant **ALLERGAN SALES, LLC** is incorporated in Delaware and headquartered in Irvine, California. Allergan Sales, LLC is the current New Drug Application (“NDA”) holder for Kadian, and in 2016, Allergan Sales, LLC held the Abbreviated New Drug

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

Applications (“ANDAs”) for Norco.³² Allergan Sales, LLC is the wholly-owned subsidiary of Allergan plc.

74. Defendant **ALLERGAN USA, INC.** is incorporated in Delaware and headquartered in Madison, New Jersey. Allergan USA, Inc. is currently responsible for Norco and Kadian sales. Allergan USA, Inc. is a wholly-owned subsidiary of Allergan plc.

75. Defendant **WATSON LABORATORIES, INC.** is a Nevada corporation with its principal place of business in Corona, California. Watson Laboratories, Inc. was sold to Teva Pharmaceutical Industries Ltd. as part of Allergan plc’s 2016 sale of its generic businesses to Teva. Prior to the sale, Watson Laboratories, Inc. was a direct subsidiary of Actavis, Inc., (n/k/a Allergan Finance, LLC). Between 2000 and 2015, Watson Laboratories, Inc. held the ANDAs for Norco and was the manufacturer of the drug. Watson Laboratories, Inc. was also the ANDA holder of various generic opioids.

76. Defendant **WARNER CHILCOTT COMPANY, LLC** is a limited liability company incorporated in Puerto Rico. Since 2015, Warner Chilcott Company, LLC has been the manufacturer of Norco. Warner Chilcott Company, LLC was a subsidiary of Warner Chilcott plc until Warner Chilcott plc became a wholly owned subsidiary of Allergan plc in 2013. Warner Chilcott Company LLC was sold to Teva Pharmaceutical Industries Ltd. as part of Allergan plc’s 2016 sale of its generic businesses to Teva.

77. Defendant **ACTAVIS PHARMA, INC.** (f/k/a Watson Pharma, Inc.) is registered to do business with the West Virginia Secretary of State as a Delaware corporation with its principal place of business in New Jersey. Actavis Pharma, Inc. (f/k/a Watson Pharma, Inc.) was

³² The Norco ANDAs are currently held by Allergan Pharmaceuticals International Limited, which is incorporated in Ireland.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

previously responsible for sales of Kadian and Norco. Actavis Pharma, Inc. was sold to Teva Pharmaceutical Industries Ltd. as part of Allergan plc's 2016 sale of its generic businesses to Teva.

78. Defendant **ACTAVIS SOUTH ATLANTIC LLC** is a Delaware limited liability company with its principal place of business in Sunrise, Florida. Actavis South Atlantic LLC was listed as the ANDA holder for oxymorphone and fentanyl transdermal. Actavis South Atlantic LLC was sold to Teva Pharmaceutical Industries Ltd. as part of Allergan plc's 2016 sale of its generic businesses to Teva.

79. Defendant **ACTAVIS ELIZABETH LLC** is a Delaware limited liability company with its principal place of business in Elizabeth, New Jersey. From December 19, 2005, until it purchased the medication in December 2008, Actavis Elizabeth LLC served as the contract manufacturer of Kadian for Alpharma. Actavis Elizabeth LLC held the NDA for Kadian from 2008 to 2013. Actavis Elizabeth LLC was also the holder of ANDAs for the following Schedule II opioid products: oxycodone/acetaminophen; homatropine methylbromide/hydrocodone bitartrate; morphine sulfate capsule; morphine sulfate tablet; oxycodone/hydrochloride tablet; oxycodone/ibuprofen; and oxymorphone tablet. Actavis Elizabeth LLC was sold to Teva Pharmaceutical Industries Ltd. as part of Allergan plc's 2016 sale of its generic businesses to Teva.

80. Defendant **ACTAVIS MID ATLANTIC LLC** is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey. Actavis Mid Atlantic LLC has held the ANDA for homatropine methylbromide/hydrocodone bitartrate. Actavis Mid Atlantic LLC was sold to Teva Pharmaceutical Industries Ltd. as part of Allergan plc's 2016 sale of its generic businesses to Teva.

81. Defendant **ACTAVIS TOTOWA LLC** is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey. Actavis Totowa LLC has held the

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

ANDAs for the following Schedule II opioid products: oxycodone/acetaminophen; homatropine methylbromide; oxycodone/hydrochloride.

82. Defendant **ACTAVIS LLC** is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey. Defendants Actavis South Atlantic LLC, Actavis Elizabeth LLC, Actavis Mid Atlantic LLC, and Actavis Totowa LLC were all direct subsidiaries of Actavis LLC, which was an indirect subsidiary of defendant Watson Laboratories, Inc. Watson Laboratories, Inc., in turn, was a direct subsidiary of Actavis, Inc. (n/k/a Allergan Finance, LLC). Actavis LLC was sold to Teva Pharmaceutical Industries Ltd. as part of Allergan plc's 2016 sale of its generic businesses to Teva.

83. Defendant **ACTAVIS KADIAN LLC** is a Delaware limited liability company with its principal place of business in Morristown, New Jersey. Actavis Kadian LLC has been identified on Kadian's label as a manufacturer or distributor of Kadian. Actavis Kadian LLC was sold to Teva Pharmaceutical Industries Ltd. as part of Allergan plc's 2016 sale of its generic businesses to Teva.

84. Defendant **ACTAVIS LABORATORIES UT, INC.** (f/k/a Watson Laboratories, Inc.-Salt Lake City) is a Delaware limited liability company with its principal place of business in Salt Lake City, Utah. Actavis Laboratories UT, Inc. was the Kadian NDA holder from 2013 to 2016 and was listed as the NDA holder for morphine sulfate capsule. Actavis Laboratories UT, Inc. was sold to Teva Pharmaceutical Industries Limited as part of Allergan plc's 2016 sale of its generic businesses to Teva. Prior to the sale, Actavis Laboratories UT, Inc. was a direct subsidiary of Actavis, Inc. (n/k/a Allergan Finance, LLC).

85. Defendant **ACTAVIS LABORATORIES FL, INC.** (f/k/a Watson Laboratories, Inc.-Florida) is a Florida limited liability company with its principal place of business in Davie,

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

Florida. Actavis Laboratories FL, Inc. was a Norco ANDA holder in 2015 and was the ANDA holder of the following Schedule II opioid products: hydrocodone/acetaminophen; hydrocodone/ibuprofen; oxycodone/aspirin; and hydromorphone tablet. Actavis Laboratories FL, Inc. was sold to Teva Pharmaceutical Industries Ltd. as part of Allergan plc's 2016 sale of its generic businesses to Teva. Prior to the sale, Actavis Laboratories FL, Inc. was a direct subsidiary of Andrx Corporation, which was a direct subsidiary of Actavis, Inc. (n/k/a Allergan Finance, LLC). Andrx Corporation was transferred to Teva as part of the 2016 sale.

86. Each of these defendants and entities currently is or was previously owned by Defendant Allergan plc, which uses them to market and sell its drugs in the United States. Collectively, these defendants and entities, and their DEA registrant subsidiaries and affiliates that manufacture, promote, distribute, and sell prescription opioids, are referred to as "**Actavis**."

87. Actavis has engaged in the manufacture, promotion, distribution, and sale of the branded and generic prescription opioid drugs sold throughout the country, including into West Virginia and Cabell County.

88. Actavis manufactures or has manufactured the following drugs as well as generic versions of Kadian, Duragesic, and Opana in the United States:

Product Name	Chemical Name	Schedule
Kadian	Morphine sulfate, extended release	Schedule II
Norco	Hydrocodone bitartrate and acetaminophen	Schedule II

4. Janssen Entities

89. Defendant **JOHNSON & JOHNSON** ("J&J") is a New Jersey corporation with its principal place of business in New Brunswick, New Jersey.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

90. Defendant **JANSSEN PHARMACEUTICALS, INC.** (“Janssen Pharmaceuticals”) is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey, and is a wholly-owned subsidiary of J&J. J&J corresponds with the FDA regarding Janssen’s products. Janssen Pharmaceuticals, Inc. formerly was known as Ortho-McNeil-Janssen Pharmaceuticals, Inc., which in turn was formerly known as Janssen Pharmaceutica, Inc.

91. Defendant **NORAMCO, INC.** (“Noramco”) is a Delaware company headquartered in Wilmington, Delaware with offices in Athens, Georgia and Schaffhausen, Switzerland. Noramco was a wholly owned subsidiary of J&J and its manufacturer of active pharmaceutical ingredients until July 2016 when J&J sold its interests to SK Capital Partners LP, a limited partnership incorporated in Delaware.

92. Defendant **ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC.** (“OMP”), now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey.

93. Defendant **JANSSEN PHARMACEUTICA, INC.** (“Janssen Pharmaceutica”), now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey.

94. Defendant, **TASMANIAN ALKALOIDS PTY LTD.** (“Tasmanian Alkaloids”) is an Australian private company based in Westbury, Australia and incorporated in Tasmania, Australia. Tasmanian Alkaloids Pty Ltd. was a wholly owned subsidiary of J&J until July 2016 when J&J sold its interests to SK Capital Partners LP, a limited partnership incorporated in Delaware.

95. J&J, Janssen Pharmaceuticals, OMP, Janssen Pharmaceutica, Noramco, and Tasmanian Alkaloids Pty Ltd. (collectively, “**Janssen**”) are or have been engaged in the

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

manufacture, promotion, distribution, and sale of opioids nationally. Among the drugs Janssen manufactures or manufactured are the following:

Product Name	Chemical Name	Schedule
Duragesic	Fentanyl	Schedule II
Nucynta ³³	Tapentadol hydrochloride, immediate release	Schedule II
Nucynta ER	Tapentadol hydrochloride, extended release	Schedule II

96. Janssen made thousands of payments to physicians nationwide, ostensibly for activities including participating on speakers' bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services, but in fact to deceptively promote and maximize the use of opioids. Together, Nucynta and Nucynta ER accounted for \$172 million in sales in 2014. Prior to 2009, Duragesic accounted for at least \$1 billion in annual sales.

97. Information from the U.S. Department of Justice's Office of the Inspector General shows that J&J made payments to prescribers, but does not indicate which drug was being promoted when J&J made these payments.

98. Prior to 2016, Janssen also had a global Active Pharmaceutical Ingredients (API) Manufacturing Network for opiate analgesics and antagonists and was among the largest narcotic API suppliers in the United States. Tasmanian Alkaloids created, manufactured and patented a new, more potent strand of poppy (high thebaine) and delivered it via intercompany transfer to Noramco. Part of the J&J Family of Companies, Noramco and Tasmanian Alkaloids are "sister companies" ³⁴ operating in a backward integration model to control the supply chain of opioid materials for production of "high-purity controlled substances."³⁵ Noramco's product portfolio

³³ Depomed, Inc. acquired the rights to Nucynta and Nucynta ER from Janssen in 2015.

³⁴ <https://www.noramco.com/our-capabilities/> (Last visited: May 15, 2019).

³⁵ Backward integration is "a form of vertical integration in which a company expands its role to fulfill tasks

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

included Oxycodone (Oxycontin, Percocet, Roxicodone), Hydrocodone (Vicodin, Lortab), Morphine (MS Contin, Embeda) in addition to Naloxone (Narcan, Exalgo) for overdose and abuse.³⁶ Noramco supplied Teva, Endo, Purdue, and Mallinckrodt. In 2015, 80% of Normaco's sales were via long-term supply agreements and/or majority controlled substance share with all 7 of the top U.S. generic companies.³⁷ Noramco steadily gained US market share and capitalized on key brand to generic switches. Janssen, like many other companies, has a corporate code of conduct, which clarifies the organization's mission, values and principles. Janssen's employees are required to read, understand and follow its Code of Conduct for Health Care Compliance. J&J imposes this code of conduct on Janssen as a pharmaceutical subsidiary of J&J. Documents posted on J&J's and Janssen's websites confirm J&J's control of the development and marketing of opioids by Janssen. Janssen's website "Ethical Code for the Conduct of Research and Development," names only J&J and does not mention Janssen anywhere within the document. The "Ethical Code for the Conduct of Research and Development" posted on the Janssen website is J&J's company-wide Ethical Code, which it requires all of its subsidiaries to follow.

99. The "Every Day Health Care Compliance Code of Conduct" posted on Janssen's website is a J&J company-wide document that describes Janssen as one of the "Pharmaceutical Companies of J&J" and as one of the "J&J Pharmaceutical Affiliates." It governs how "[a]ll employees of J&J Pharmaceutical Affiliates," including those of Janssen, "market, sell, promote, research, develop, inform and advertise J&J Pharmaceutical Affiliates' products." All Janssen officers, directors, employees, sales associates must certify that they have "read, understood and will abide by" the code. The code governs all of the forms of marketing at issue in this case.

formerly completed by businesses up the supply chain."

<https://www.investopedia.com/terms/b/backwardintegration.asp> (Last visited: May 21, 2019).

³⁶ PAR_OPIOID_MDL_0002024206

³⁷ PAR_OPIOID_MDL_0002024217

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER**5. Endo Entities**

100. Defendant **ENDO HEALTH SOLUTIONS INC.** (“EHS”) is a Delaware corporation with its principal place of business in Malvern, Pennsylvania.

101. Defendant **ENDO PHARMACEUTICALS, INC.** (“EPI”) is a wholly-owned subsidiary of EHS and is a Delaware corporation with its principal place of business in Malvern, Pennsylvania.

102. Defendant **PAR PHARMACEUTICAL, INC.** is a Delaware corporation with its principal place of business located in Chestnut Ridge, New York. Par Pharmaceutical, Inc. is a wholly-owned subsidiary of Par Pharmaceutical Companies, Inc. f/k/a Par Pharmaceutical Holdings, Inc. Defendant Par Pharmaceuticals Companies, Inc. is a Delaware corporation with its principal place of business located in Chestnut Ridge, New York (Par Pharmaceutical, Inc. and Par Pharmaceutical Companies, Inc. collectively, “Par Pharmaceutical”). Par Pharmaceutical was acquired by Endo International plc in September 2015 and is an operating company of Endo International plc. EHS, EPI, and Par Pharmaceutical, and their DEA registrant subsidiaries and affiliates (collectively, “**Endo**”) manufacture opioids sold nationally, and in Huntington. Among the drugs Endo manufactures or manufactured are the following:

Product Name	Chemical Name	Schedule
Opana ER	Oxymorphone hydrochloride, extended release	Schedule II
Opana	Oxymorphone hydrochloride	Schedule II
Percodan	Oxymorphone hydrochloride and aspirin	Schedule II
Percocet	Oxymorphone hydrochloride and acetaminophen	Schedule II
Generic	Oxycodone	Schedule II
Generic	Oxymorphone	Schedule II
Generic	Hydromorphone	Schedule II
Generic	Hydrocodone	Schedule II

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

103. Endo made thousands of payments to physicians nationwide ostensibly for activities including participating on speakers' bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services, but in fact to deceptively promote and maximize the use of opioids.

104. Opioids made up roughly \$403 million of Endo's overall revenues of \$3 billion in 2012, accounting for over 10% of Endo's total revenue; Opana ER yielded revenue of \$1.15 billion from 2010 to 2013. Endo also manufactures and sells generic opioids, both directly and through its subsidiaries, Par Pharmaceutical and Qualitest Pharmaceuticals, Inc., including generic oxycodone, oxymorphone, hydromorphone, and hydrocodone products.

105. The Food and Drug Administration requested that Endo remove Opana ER from the market in June 2017. The FDA relied on post-marketing data in reaching its conclusion based on risk of abuse.

6. Cephalon Entities

106. Defendant **TEVA PHARMACEUTICALS USA, INC.** ("Teva USA") is a Delaware corporation with its principal place of business in North Wales, Pennsylvania. Teva USA was in the business of selling generic opioids, including a generic form of OxyContin from 2005 to 2009. Teva USA is a wholly-owned subsidiary of Defendant **Teva Pharmaceutical Industries, Ltd.** ("Teva Ltd."), an Israeli corporation (collectively "Teva").

107. Defendant **CEPHALON, INC.** is a Delaware corporation with its principal place of business in Frazer, Pennsylvania. In 2011, Teva Ltd. acquired Cephalon, Inc. In 2016, Teva Ltd acquired Allergan plc's generic businesses.

108. Teva USA and Cephalon, Inc. and their DEA registrant subsidiaries and affiliates (collectively, "**Cephalon**") work together to manufacture, promote, distribute and sell both brand

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

name and generic versions of the following opioids in the United States, Cabell County, and Plaintiff's Community:

Product Name	Chemical Name	Schedule
Actiq	Fentanyl citrate	Schedule II
Fentora	Fentanyl buccal	Schedule II

109. From 2000 forward, Cephalon has made thousands of payments to physicians nationwide, including in West Virginia, many of whom were not oncologists and did not treat cancer pain, ostensibly for activities including participating on speakers' bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services but in fact to deceptively promote and maximize the use of opioids.

7. Mallinckrodt Entities

110. Defendant **MALLINCKRODT PLC** is an Irish public limited company with its headquarters in Staines-Upon-Thames, Surrey, United Kingdom. Mallinckrodt plc was incorporated in January 2013 for the purpose of holding the pharmaceuticals business of Covidien plc, which was fully transferred to Mallinckrodt plc in June of that year. Mallinckrodt plc also operates under the registered business name Mallinckrodt Pharmaceuticals, with its U.S. headquarters in Hazelwood, Missouri.

111. Defendant **MALLINCKRODT LLC** is a Delaware corporation with its headquarters in Hazelwood, Missouri.

112. Defendant **SPECGX LLC** is a Delaware limited liability company with its headquarters in Clayton, Missouri and is a wholly-owned subsidiary of Mallinckrodt plc.

113. Mallinckrodt plc, Mallinckrodt LLC, and SpecGx LLC and their DEA registrant subsidiaries and affiliates (together, "**Mallinckrodt**") manufacture, market, sell and distribute

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

pharmaceutical drugs throughout the United States. Mallinckrodt is the largest U.S. supplier of opioid pain medications and among the top ten generic pharmaceutical manufacturers in the United States, based on prescriptions.

114. Mallinckrodt manufactures and markets two branded opioids: Exalgo, which is extended-release hydromorphone, sold in 8, 12, 16, and 32 mg dosage strengths, and Roxicodone, which is oxycodone, sold in 15 and 30 mg dosage strengths. In 2009, Mallinckrodt Inc., a subsidiary of Covidien plc, acquired the U.S. rights to Exalgo. The FDA approved Exalgo for treatment of chronic pain in 2012. Mallinckrodt further expanded its branded opioid portfolio in 2012 by purchasing Roxicodone from Xanodyne Pharmaceuticals. In addition, Mallinckrodt developed Xartemis XR, an extended-release combination of oxycodone and acetaminophen, which the FDA approved in March 2014, and which Mallinckrodt has since discontinued. Mallinckrodt promoted its branded opioid products with its own direct sales force.

115. While it has sought to develop its branded opioid products, Mallinckrodt has long been a leading manufacturer of generic opioids. Mallinckrodt estimated that in 2015 it received approximately 25% of the U.S. Drug Enforcement Administration's ("DEA") entire annual quota for controlled substances that it manufactures. Mallinckrodt also estimated, based on IMS Health data for the same period, that its generics claimed an approximately 23% market share of DEA Schedules II and III opioid and oral solid dose medications.

116. Mallinckrodt operates a vertically integrated business in the United States: (1) importing raw opioid materials and selling opioid API to other opioid manufacturers, (2) manufacturing generic opioid products, primarily at its facility in Hobart, New York, and (3) marketing and selling its products to drug distributors, specialty pharmaceutical distributors,

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

retail pharmacy chains, pharmaceutical benefit managers that have mail-order pharmacies, and hospital buying groups.

117. Among the drugs Mallinckrodt manufactures or has manufactured are the following:

Product Name	Chemical Name	Schedule
Exalgo	Hydromorphone hydrochloride, extended release	Schedule II
Roxicodone	Oxycodone hydrochloride	Schedule II
Xartemis XR	Oxycodone hydrochloride and acetaminophen	Schedule II
Methadose	Methadone hydrochloride	Schedule II
Generic	Morphine sulfate, extended release	Schedule II
Generic	Morphine sulfate oral solution	Schedule II
Generic	Fentanyl transdermal system	Schedule II
Generic	Oral transmucosal fentanyl citrate	Schedule II
Generic	Oxycodone and acetaminophen	Schedule II
Generic	Hydrocodone bitartrate and acetaminophen	Schedule II
Generic	Hydromorphone hydrochloride	Schedule II
Generic	Hydromorphone hydrochloride, extended release	Schedule II
Generic	Naltrexone hydrochloride	unscheduled
Generic	Oxymorphone hydrochloride	Schedule II
Generic	Methadone hydrochloride	Schedule II
Generic	Oxycodone hydrochloride	Schedule II
Generic	Buprenorphine and naloxone	Schedule III

118. Mallinckrodt made thousands of payments to physicians nationwide ostensibly for activities including participating on speakers' bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services, but in fact to deceptively promote and maximize the use of opioids.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

8. KVK Tech

119. Defendant **KVK-TECH, INC.** is a privately held Pennsylvania corporation with its principal place of business in Pennsylvania. KVK-Tech, Inc. is a manufacturer of generic prescription opioids, including many Schedule II controlled substances such as Oxycodone and Hydrocodone.

120. KVK-Tech, Inc. has engaged in the manufacture, promotion, distribution, and sale of the generic prescription opioid drugs sold throughout the country, including into West Virginia and Cabell County.

9. Amneal Pharmaceuticals

121. Defendant **AMNEAL PHARMACEUTICALS LLC** is a Delaware limited liability company with its principal place of business in Bridgewater, New Jersey. Impax laboratories, LLC, formerly known as Impax Laboratories, Inc., is a Delaware limited liability company with its principle place of business in Bridgewater, New Jersey. Upon information and belief, in May 2018, Impax laboratories, Inc. merged with and into Amneal pharmaceuticals LLC to form Defendant, Amneal Pharmaceuticals, Inc., a Delaware Corporation with its principal place of business in Bridgewater, New Jersey. Defendant Amneal Pharmaceuticals of New York LLC is a Delaware limited liability company with its principal place of business in Hauppauge, New York. Amneal Pharmaceuticals, Inc., Amneal Pharmaceuticals LLC, Amneal Pharmaceuticals of New York LLC, and Impax Laboratories, LLC are collectively referred to as “Amneal.” Amneal manufactures, promotes, distributes and/or sells opioids nationally and in Cabell County and the City of Huntington.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

122. Collectively, Purdue, Actavis, Janssen, Endo, Cephalon, Mallinckrodt, KVK Tech and Amneal Pharmaceuticals are referred to as “**Manufacturer Defendants**” and are also included within the definition of “**Marketing Defendants**.³⁸

123. Manufacturer Defendants and Marketing Defendants each include the above referenced entities as well as their predecessors, successors, affiliates, subsidiaries, partnerships and divisions to the extent that they are engaged in the distribution, sale and/or dispensing of opioids.

B. Distributor Defendants

124. The **Distributor Defendants** are defined below. At all relevant times, the Distributor Defendants have distributed, supplied, sold, and placed into the stream of commerce the prescription opioids, without fulfilling the fundamental duty of drug distributors to detect, warn, and prevent diversion of dangerous drugs. The Distributor Defendants universally failed to comply with federal and/or state law, including their duty to maintain effective control against diversion of prescription opioids.³⁹

125. The Distributor Defendants are engaged in distribution and/or “wholesale distribution” as defined under state and federal law. Plaintiff alleges the unlawful conduct by the Distributor Defendants is a substantial cause for the volume of prescription opioids plaguing Plaintiffs’ Community.

126. The Distributor Defendants also engaged in the marketing of opioids with and for the Manufacturer Defendants. They sold data to Manufacturer Defendants to allow them to better target their sales and marketing efforts, entered into agreements to and did market opioids, and ran

³⁸ Together, Purdue, Cephalon, Janssen, Actavis and Endo are also sometimes referred to as “RICO Marketing Defendants.”

³⁹ 21 U.S.C. § 823(b)(1); 21 C.F.R. § 1301.71.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

refill, adherence, and mandated REMS programs for Manufacturer Defendants, among other activities. In short, both Manufacturer and Distributor Defendants were engaged, fully, collectively and in concert, in the marketing and distribution sides of the opioid business.

1. AmerisourceBergen

127. Defendant **AMERISOURCEBERGEN DRUG CORPORATION** (“AmerisourceBergen” or “ABDC”), is a Delaware corporation with its principal place of business in Chesterbrook, Pennsylvania.

128. AmerisourceBergen is a DEA registered “distributor” of prescription opioids⁴⁰ and owes a duty to maintain effective control against diversion of prescription opioids.⁴¹

129. Through its various DEA registered subsidiaries and affiliated entities, AmerisourceBergen distributes pharmaceutical drugs, including opioids, throughout the country, including into West Virginia, Cabell County, and the City of Huntington.

130. AmerisourceBergen, at all relevant times, operated as licensed distributor wholesaler in West Virginia, licensed by the West Virginia Board of Pharmacy.

131. Between 2006 and 2014, AmerisourceBergen distributed ***more than [REDACTED]*** ***doses of hydrocodone and oxycodone*** into Cabell County, West Virginia.⁴²

132. AmerisourceBergen is the eleventh largest company by revenue in the United States, with annual revenue of \$147 billion in 2016.

⁴⁰ 21 U.S.C. §802(11) and §822(a)(1)

⁴¹ 21 U.S.C. § 823(b)(1).

⁴² See ARCOS Data produced in MDL 2804.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

2. Cardinal Health

133. Defendant **CARDINAL HEALTH, INC.** (“Cardinal” or “Cardinal Health”) is an Ohio corporation with its principal place of business in Dublin, Ohio.

134. Cardinal Health is a DEA registered “distributor” of prescription opioids⁴³ and owes a duty to maintain effective control against diversion of prescription opioids.⁴⁴

135. Through its various DEA registered subsidiaries and affiliated entities, Cardinal Health distributes pharmaceutical drugs, including opioids, throughout the country, including into West Virginia and Cabell County.

136. Cardinal Health, at all relevant times, operated as licensed distributor wholesaler in West Virginia, licensed by the West Virginia Board of Pharmacy.

137. Between 2006 and 2014, Cardinal Health distributed ***more than [REDACTED] doses of hydrocodone and oxycodone*** into Plaintiffs’ community.⁴⁵

138. Cardinal Health describes itself as a “global, integrated health care services and products company,” and is the fifteenth largest company by revenue in the United States, with annual revenue of \$121 billion in 2016.

139. Based on Cardinal Health’s own estimates, one of every six pharmaceutical products dispensed to United States patients travels through the Cardinal Health network.

3. McKesson

140. Defendant, **MCKESSON CORPORATION** (“McKesson”), is a Delaware corporation with its principal place of business in San Francisco, California.

⁴³ 21 U.S.C. §802(11) and §822(a)(1)

⁴⁴ 21 U.S.C. § 823(b)(1).

⁴⁵ See ARCOS Data produced in MDL 2804.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

141. McKesson is a DEA registered “distributor” of prescription opioids and owes a duty to maintain effective control against diversion of prescription opioids.

142. Through its various DEA registered subsidiaries and affiliated entities, McKesson distributes pharmaceutical drugs, including opioids, throughout the country, including into City of Huntington and Cabell County.

143. McKesson, at all relevant times, operated as licensed distributor wholesaler in West Virginia, licensed by the West Virginia Board of Pharmacy.

144. Between 2006 and 2014, McKesson distributed more than [REDACTED] doses of *hydrocodone and oxycodone* into Plaintiffs’ Community.⁴⁶

145. McKesson is fifth on the list of Fortune 500 companies, ranking immediately after Apple and ExxonMobil, with annual revenue of \$191 billion in 2016.

4. H.D. Smith Wholesale Drug Co.

146. Defendant **H. D. SMITH WHOLESALE DRUG CO.** (“H.D. Smith”), through its various DEA registered subsidiaries and affiliated entities, is a wholesaler of pharmaceutical drugs that distributes opioids throughout the country, including in Plaintiff’s Community.

147. H.D. Smith, at all relevant times, operated as a licensed distributor wholesaler in West Virginia, licensed by the West Virginia Board of Pharmacy.

148. H. D. Smith is a Delaware corporation with its principal place of business in Springfield, Illinois. H. D. Smith is a privately held independent pharmaceuticals distributor of wholesale brand, generic and specialty pharmaceuticals.

149. At all times relevant to this Complaint, H.D. Smith distributed prescription opioids throughout the United States, including in West Virginia and Cabell County.

⁴⁶ See ARCOS Data produced in MDL 2804.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

150. At all relevant times, H. D. Smith operated as a licensed distributor in West Virginia, licensed by the West Virginia Board of Pharmacy.

5. CVS

151. Defendant **CVS HEALTH CORPORATION** is a Delaware corporation with its principal place of business in Rhode Island.

152. Defendant **CVS PHARMACY, INC.** is Rhode Island corporation with its principal place of business in Woonsocket, Rhode Island. CVS Pharmacy, Inc. is a wholly owned subsidiary of CVS Health Corporation.

153. Defendant CVS Pharmacy, Inc. is both a DEA registered “distributor”⁴⁷ and a DEA registered “dispenser”⁴⁸ of prescription opioids.

154. CVS Pharmacy, Inc. and its DEA registered distribution subsidiaries owe a duty as distributors to maintain effective control against diversion of prescription opioids.⁴⁹

155. CVS Pharmacy, Inc. and its DEA registered dispensing subsidiaries also owe a duty as dispensers provide effective controls and procedures to guard against diversion of controlled substances in its role.⁵⁰

156. As a distributor, CVS Pharmacy Inc. acted by and through its own various DEA registered subsidiaries and affiliated entities to distribute pharmaceutical drugs, including opioids, throughout the country, including into West Virginia and Cabell County.

157. Defendant CVS Pharmacy Inc. distributed prescription opioids Plaintiffs’ Community through the following wholly owned subsidiaries:

⁴⁷ 21 U.S.C. §802(11) and §822(a)(1).

⁴⁸ 21 U.S.C. §802(10) and §822(a)(2).

⁴⁹ 21 U.S.C. § 823(b)(1)

⁵⁰ 21 C.F.R. § 1301.71.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

- a. Defendant **CVS INDIANA L.L.C.**, an Indiana limited liability company with its principal place of business in Indianapolis, Indiana;
- b. Defendant **CVS RX SERVICES, INC.** (DBA: CVS Pharmacy Distribution Center), a New York corporation with its principal place of business in Woonsocket, RI; and
- c. Defendant **CVS TENNESSEE DISTRIBUTION, L.L.C.** a Tennessee corporation with its principal place of business in Woonsocket, Rhode Island.

158. CVS Pharmacy, Inc. instituted, set-up, ran, directed, and staffed with its own employees, the majority of the Suspicious Order Monitoring and diversion control functions for CVS Indiana, LLC, CVS Rx Services, Inc. and CVS TN Distribution, LLC.

159. CVS Indiana, LLC, CVS Rx Services, Inc. and CVS TN Distribution, LLC are alter-egos of CVS Pharmacy, Inc.

160. Collectively, CVS Pharmacy, Inc., CVS Indiana, LLC, CVS Rx Services, Inc. and CVS TN Distribution, LLC are referred to herein as “CVS”.

161. As a distributor of prescription opioids, CVS distributes only to its own pharmacies.

162. Between 2006 and 2014, CVS Pharmacy Inc.,⁵¹ operated four (4) pharmacies in Cabell County, West Virginia,⁵² all located in Huntington, West Virginia: CVS/Pharmacy #03391 (DEA# BR4365486); CVS/Pharmacy #03480 (DEA# AR6055025); CVS/Pharmacy #04419 (DEA# BR4301545); CVS/Pharmacy #04425 (DEA# BR4321787).⁵³

163. These four pharmacies were owned by Defendant **WEST VIRGINIA CVS PHARMACY, LLC**, is a West Virginia limited liability company with its principal place of business in Charleston, West Virginia., whose sole member is CVS Pharmacy Inc.

⁵¹ Acting by and through its wholly owned subsidiary West Virginia Pharmacy, L.L.C.

⁵² These are the pharmacies revealed by the ARCOS data.

⁵³ Since 2014, CVS has added two (2) more pharmacies which dispense in Cabell County: CVS/Pharmacy #16810 and CVS/Pharmacy #10566.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

164. As a distributor, CVS distributed ***more than [REDACTED] doses of hydrocodone*** to these four pharmacies between 2006 and 2014.⁵⁴

165. CVS's pharmacies in Huntington, West Virginia also received distributions of prescription opioids from other Distributor Defendants, including Cardinal Health and McKesson.

166. Through these four pharmacies alone,⁵⁵ CVS dispensed ***more than [REDACTED] doses of hydrocodone and oxycodone*** between 2006 and 2014 in Cabell County, West Virginia.⁵⁶

167. CVS pharmacies sold more than **[REDACTED] additional doses** of hydrocodone and oxycodone across the river from Huntington, West Virginia in Lawrence County, Ohio (population 62,450) through three (3) pharmacies: CVS Pharmacy #03403, CVS Pharmacy #03474 and CVS #06349.⁵⁷

168. CVS pharmacies sold more than **[REDACTED] additional doses** of hydrocodone and oxycodone in Boyd County, Kentucky (population 49,542), through a single pharmacy: CVS Pharmacy #06347.⁵⁸

169. Between 2006 and 2014, CVS Pharmacy Inc. operated 24 pharmacies within a 40-mile radius of Cabell County, WV and dispensed ***more than [REDACTED] doses*** of hydrocodone and oxycodone through those pharmacies.⁵⁹

170. The sheer volume of prescription opioids distributed to and dispensed by CVS pharmacies in and around Cabell County is indicative of diversion.

⁵⁴ See ARCOS Data produced in MDL 2804.

⁵⁵ CVS/Pharmacy #03391 (DEA# BR4365486); CVS/Pharmacy #03480 (DEA# AR6055025); CVS/Pharmacy #04419 (DEA# BR4301545); and CVS/Pharmacy #04425 (DEA# BR4321787).

⁵⁶ See ARCOS Data produced in MDL 2804.

⁵⁷ See ARCOS Data produced in MDL 2804.

⁵⁸ See ARCOS Data produced in MDL 2804.

⁵⁹ See ARCOS Data produced in MDL 2804.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

171. As a vertically integrated distributor and dispenser of prescription opioids, CVS knew or should have known that an excessive volume of pills was being sold into Huntington and Cabell County, West Virginia.

172. Discovery will reveal that CVS knew or should have known that its pharmacies in the Tri-State area (West Virginia, Ohio, and Kentucky) were (a) filling multiple prescriptions to the same patient using the same doctor (b) filling multiple prescriptions by the same patient using different doctors (c) filling prescriptions of unusual size and frequency for the same patient (d) filling prescriptions of unusual size and frequency from out-of-state patients; (e) filling prescriptions of unusual size and frequency paid for in cash (f) filling prescriptions of unusual size and frequency from the same prescribing physician (g) filling prescriptions of unusual size and frequency from out-of-state physicians; and (h) filing prescriptions for patients and doctors in combinations that were indicative of diversion and abuse. Upon information and belief, the volumes of opioids distributed to and dispensed by these pharmacies were disproportionate to non-controlled drugs and other products sold by these pharmacies, and disproportionate to the sales of opioids in similarly sized pharmacy markets.

173. As a National Pharmacy, CVS also had duties to: establish policies and procedures that were effective and sufficient to avoid filling prescriptions indicative of potential abuse or diversion, to train and evaluate their employees on their compliance with these policies and procedures; and to avoid policies and procedures, such as limits on wait time or volume incentives, that made it impossible or unlikely that employees would be willing and able to identify and prevent diversion of opioids. Additional, National Pharmacies were obligated to report potential diversion to the DEA and/or other appropriate law enforcement and regulatory authorities.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

174. At all relevant times, and as the parent company of the Defendant CVS Pharmacy, Inc., established national policies and procedures governing the distribution and dispensing of controlled substances throughout the United States that it directed and intended that those policies and procedures would be implemented on a nationwide basis including, specifically, West Virginia. At all times relevant to this Complaint, Defendant CVS Pharmacy, Inc. was responsible for directing and implementing policies and procedures governing the distribution and dispensing of controlled substances by its subsidiaries, including but not limited to the Rite Aid Subsidiaries, throughout the United States, including in West Virginia and Plaintiffs' Community specifically.

175. CVS Pharmacy, Inc. had complete access to, and full visibility of, all prescription opioid distribution data related CVS pharmacies in and around Huntington and Cabell County, West Virginia.

176. CVS Pharmacy, Inc. had complete access to, and full visibility of, all prescription opioid dispensing data related CVS pharmacies in and around Huntington and Cabell County, West Virginia.

177. CVS Pharmacy, Inc. had complete access to information revealing the doctors who prescribed the prescription opioids dispensed in CVS pharmacies in and around Huntington and Cabell County, West Virginia.

178. CVS Pharmacy, Inc. had complete access to information revealing the customers which filled (or sought to fill) prescriptions for opioids in CVS pharmacies in and around Huntington and Cabell County, West Virginia.

179. CVS Pharmacy, Inc. had complete access to information revealing the opioid and non-opioid prescriptions dispensed by CVS pharmacies in Huntington and Cabell County, West Virginia, including those which were being paid for in cash.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

180. CVS Pharmacy, Inc. had complete access to information revealing the geographic location of out-of-state doctors whose prescriptions for opioids were being filled in and around Huntington and Cabell County, West Virginia.

181. CVS Pharmacy, Inc. had complete access to information revealing the size, dosage, and frequency of prescriptions written by specific doctors across their pharmacies in and around Huntington and Cabell County, West Virginia.

182. Defendants CVS Pharmacy, Inc., CVS Indiana, L.L.C., CVS Rx Services, Inc., and CVS TN Distribution, LLC are collectively referred to herein as “CVS”.

6. Rite Aid

183. Defendant **RITE AID CORPORATION** is a Delaware corporation with its principal office located in Camp Hill, Pennsylvania. Rite Aid, through its various DEA registered subsidiaries and affiliated entities, conducts business as a licensed wholesale distributor.

184. Defendant **RITE AID OF MARYLAND, INC.**, d/b/a Rite Aid Mid-Atlantic Customer Support Center, Inc., is a Maryland corporation with its principal office located in Camp Hill, Pennsylvania. At all times relevant to this Complaint, Rite Aid of Maryland, Inc., d/b/a Rite Aid Mid-Atlantic Customer Support Center, Inc. distributed prescription opioids throughout the United States, including in Huntington specifically.

185. During the relevant time period, and as further alleged below, Rite Aid entities also owned and operated pharmacies in Cabell County and Huntington West Virginia, through Defendant **RITE AID OF WEST VIRGINIA, INC.**, a West Virginia corporation with its principal place of business in Camp Hill, Pennsylvania.

186. Rite Aid of West Virginia was in the business of holding and operating retail pharmacies in West Virginia, including in Plaintiff’s Community, on behalf of its parent company Rite Aid Corporation. Rite Aid of West Virginia orders of controlled substances from Rite Aid of

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

Maryland. These controlled substances are distributed and dispensed according to practices and procedures established by Rite Aid Corporation.

187. Defendants Rite Aid of Maryland, Inc., d/b/a Rite Aid Mid-Atlantic Customer Support Center, Inc. and Rite Aid of West Virginia, Inc. are collectively referred to as the “**Rite Aid Subsidiaries**.”

188. Defendants Rite Aid Corporation, Rite Aid of Maryland, Inc., d/b/a Rite Aid Mid-Atlantic Customer Support Center, Inc., and Rite Aid of West Virginia are further collectively referred to herein as “**Rite Aid**.”

189. At all relevant times, and as the parent company of the Rite Aid Subsidiaries, Defendant Rite Aid Corporation established national policies and procedures governing the distribution and dispensing of controlled substances throughout the United States that it directed and intended that those policies and procedures would be implemented on a nationwide basis including, specifically, West Virginia. At all times relevant to this Complaint, Defendant Rite Aid Corporation was responsible for directing and implementing policies and procedures governing the distribution and dispensing of controlled substances by its subsidiaries, including but not limited to the Rite Aid Subsidiaries, throughout the United States, including in West Virginia and Plaintiffs’ Community specifically.

190. As a distributor of prescription opioids, Rite Aid distributes only to its own pharmacies.

191. Rite Aid pharmacies in Cabell County and Huntington, West Virginia also received distributions of prescription opioids from other Distributor Defendants.

192. The volume of prescription opioids distributed to and dispensed by Rite Aid pharmacies in and around Huntington and Cabell County is indicative of diversion.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

193. As a vertically integrated distributor and dispenser of prescription opioids, Rite Aid knew or should have known that an excessive volume of pills was being sold into Huntington and Cabell County, West Virginia.

194. Discovery will reveal that Rite-Aid knew or should have known that its pharmacies in the Tri-State area (West Virginia, Ohio, and Kentucky) were (a) filling multiple prescriptions to the same patient using the same doctor (b) filling multiple prescriptions by the same patient using different doctors (c) filling prescriptions of unusual size and frequency for the same patient (d) filling prescriptions of unusual size and frequency from out-of-state patients; (e) filling prescriptions of unusual size and frequency paid for in cash (f) filling prescriptions of unusual size and frequency from the same prescribing physician (g) filling prescriptions of unusual size and frequency from out-of-state physicians; and (h) filing prescriptions for patients and doctors in combinations that were indicative of diversion and abuse. Upon information and belief, the volumes of opioids distributed to and dispensed by these pharmacies were disproportionate to non-controlled drugs and other products sold by these pharmacies, and disproportionate to the sales of opioids in similarly sized pharmacy markets.

195. As a National Pharmacy, Rite Aid also had duties to: establish policies and procedures that were effective and sufficient to avoid filling prescriptions indicative of potential abuse or diversion, to train and evaluate their employees on their compliance with these policies and procedures; and to avoid policies and procedures, such as limits on wait time or volume incentives, that made it impossible or unlikely that employees would be willing and able to identify and prevent diversion of opioids. Additional, National Pharmacies were obligated to report potential diversion to the DEA and/or other appropriate law enforcement and regulatory authorities.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

196. Rite Aid had complete access to, and full visibility of, all prescription opioid distribution data related Rite Aid pharmacies in and around Huntington and Cabell County, West Virginia.

197. Rite Aid had complete access to, and full visibility of, all prescription opioid dispensing data related Rite Aid pharmacies in and around Huntington and Cabell County, West Virginia.

198. Rite Aid had complete access to information revealing the doctors who prescribed the prescription opioids dispensed in Rite Aid pharmacies in and around Huntington and Cabell County, West Virginia.

199. Rite Aid had complete access to information revealing the customers which filled (or sought to fill) prescriptions for opioids in Rite Aid pharmacies in and around Huntington and Cabell County, West Virginia.

200. Rite Aid had complete access to information revealing the opioids prescriptions dispensed by Rite Aid pharmacies in Huntington and Cabell County, West Virginia which were being paid for in cash.

201. Rite Aid had complete access to information revealing the geographic location of out-of-state doctors whose prescriptions for opioids were being filled in and around Huntington and Cabell County, West Virginia.

202. Rite Aid had complete access to information revealing the size and frequency of prescriptions written by specific doctors across their pharmacies in and around Huntington and Cabell County, West Virginia.

203. In addition to dispensing and distributing opioids, Rite Aid has marketed opioids during the relevant time period.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

7. Walgreens

204. Defendant **WALGREENS BOOTS ALLIANCE, INC.**, (“WBA”) is a Delaware corporation with its principal place of business in Illinois. WBA acted by and through its own various DEA registered subsidiaries and affiliated entities to distribute pharmaceutical drugs, including opioids, throughout the country, including into West Virginia and Cabell County.

205. Defendant **WALGREEN CO.** is an Illinois corporation with its principal place of business in Deerfield, Illinois. Walgreen Co. conducted business as is a license wholesale distributor. At all times relevant to this Complaint, Walgreen Co. distributed prescription opioids throughout the United States, including into West Virginia and Cabell County.

206. Defendant **WALGREEN EASTERN CO.** is a New York corporation with its principal place of business in Deerfield, Illinois. Walgreen Eastern Co. conducts business as a licensed wholesale distributor. At all times relevant to this Complaint, Walgreen Eastern Co. distributed prescription opioids throughout the United States, including into West Virginia and Cabell County.

207. WBA, Walgreen Co., and Walgreen Eastern Co. are collectively referred to herein as “Walgreens”.

208. During the relevant time period, and as further alleged below, Walgreens entities also owned and operated pharmacies in Cabell County and Huntington, West Virginia.

209. As a distributor of prescription opioids, Walgreens distributes only to its own pharmacies.

210. Walgreens pharmacies in Cabell County and Huntington, West Virginia also received distributions of prescription opioids from other Distributor Defendants.

211. The volume of prescription opioids distributed to and dispensed by Walgreens pharmacies in and around Huntington and Cabell County is indicative of diversion.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

212. As a vertically integrated distributor and dispenser of prescription opioids, Walgreens knew or should have known that an excessive volume of pills was being sold into Huntington and Cabell County, West Virginia.

213. Discovery will reveal that Walgreens knew or should have known that its pharmacies in the Tri-State area (West Virginia, Ohio, and Kentucky) were (a) filling multiple prescriptions to the same patient using the same doctor (b) filling multiple prescriptions by the same patient using different doctors (c) filling prescriptions of unusual size and frequency for the same patient (d) filling prescriptions of unusual size and frequency from out-of-state patients; (e) filling prescriptions of unusual size and frequency paid for in cash (f) filling prescriptions of unusual size and frequency from the same prescribing physician (g) filling prescriptions of unusual size and frequency from out-of-state physicians; and (h) filing prescriptions for patients and doctors in combinations that were indicative of diversion and abuse. Upon information and belief, the volumes of opioids distributed to and dispensed by these pharmacies were disproportionate to non-controlled drugs and other products sold by these pharmacies, and disproportionate to the sales of opioids in similarly sized pharmacy markets.

214. Walgreens had complete access to, and full visibility of, all prescription opioid distribution data related Walgreens pharmacies in and around Huntington and Cabell County, West Virginia.

215. Walgreens had complete access to, and full visibility of, all prescription opioid dispensing data related Walgreens pharmacies in and around Huntington and Cabell County, West Virginia.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

216. Walgreens had complete access to information revealing the doctors who prescribed the prescription opioids dispensed in Walgreens pharmacies in and around Huntington and Cabell County, West Virginia.

217. Walgreens had complete access to information revealing the customers which filled (or sought to fill) prescriptions for opioids in Walgreens pharmacies in and around Huntington and Cabell County, West Virginia.

218. Walgreens had complete access to information revealing the opioids prescriptions dispensed by Walgreens pharmacies in Huntington and Cabell County, West Virginia which were being paid for in cash.

219. Walgreens had complete access to information revealing the geographic location of out-of-state doctors whose prescriptions for opioids were being filled in and around Huntington and Cabell County, West Virginia.

220. Walgreens had complete access to information revealing the size and frequency of prescriptions written by specific doctors across their pharmacies in and around Huntington and Cabell County, West Virginia.

221. In addition to dispensing and distributing opioids, Walgreens has marketed opioids during the relevant time period.

8. Kroger

222. Defendant **KROGER LIMITED PARTNERSHIP I** is an Ohio corporation with its principal place of business located in Cincinnati, Ohio.

223. Defendant **KROGER LIMITED PARTNERSHIP II** is also an Ohio corporation with its principal place of business located in Cincinnati, Ohio.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

224. At all times relevant to this Complaint, Kroger Distributors distributed prescription opioids throughout the United States, including in Cabell County and the City of Huntington, specifically.

225. Defendants Kroger Limited Partnership I and Kroger Limited Partnership II are collectively referred to as “Kroger.”

226. During the relevant time period, and as further alleged below, Kroger entities also owned and operated pharmacies in Cabell County and Huntington West Virginia.

227. As a distributor of prescription opioids, Kroger distributes only to its own pharmacies.

228. Kroger pharmacies in Cabell County and Huntington, West Virginia also received distributions of prescription opioids from other Distributor Defendants.

229. The volume of prescription opioids distributed to and dispensed by Kroger pharmacies in and around Huntington and Cabell County is indicative of diversion.

230. As a vertically integrated distributor and dispenser of prescription opioids, Kroger knew or should have known that an excessive volume of pills was being sold into Huntington and Cabell County, West Virginia.

231. Discovery will reveal that Kroger knew or should have known that its pharmacies in the Tri-State area (West Virginia, Ohio, and Kentucky) were (a) filling multiple prescriptions to the same patient using the same doctor (b) filling multiple prescriptions by the same patient using different doctors (c) filling prescriptions of unusual size and frequency for the same patient (d) filling prescriptions of unusual size and frequency from out-of-state patients; (e) filling prescriptions of unusual size and frequency paid for in cash (f) filling prescriptions of unusual size and frequency from the same prescribing physician (g) filling prescriptions of unusual size and

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

frequency from out-of-state physicians; and (h) filing prescriptions for patients and doctors in combinations that were indicative of diversion and abuse. Upon information and belief, the volumes of opioids distributed to and dispensed by these pharmacies were disproportionate to non-controlled drugs and other products sold by these pharmacies, and disproportionate to the sales of opioids in similarly sized pharmacy markets.

232. Kroger had complete access to, and full visibility of, all prescription opioid distribution data related Kroger pharmacies in and around Huntington and Cabell County, West Virginia.

233. Kroger had complete access to, and full visibility of, all prescription opioid dispensing data related Kroger pharmacies in and around Huntington and Cabell County, West Virginia.

234. Kroger had complete access to information revealing the doctors who prescribed the prescription opioids dispensed in Kroger pharmacies in and around Huntington and Cabell County, West Virginia.

235. Kroger had complete access to information revealing the customers which filled (or sought to fill) prescriptions for opioids in Kroger pharmacies in and around Huntington and Cabell County, West Virginia.

236. Kroger had complete access to information revealing the opioids prescriptions dispensed by Kroger pharmacies in Huntington and Cabell County, West Virginia which were being paid for in cash.

237. Kroger had complete access to information revealing the geographic location of out-of-state doctors whose prescriptions for opioids were being filled in and around Huntington and Cabell County, West Virginia.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

238. Kroger had complete access to information revealing the size and frequency of prescriptions written by specific doctors across their pharmacies in and around Huntington and Cabell County, West Virginia.

239. In addition to dispensing and distributing opioids, Kroger has marketed opioids during the relevant time period.

9. Walmart Inc.

240. Defendant **WALMART INC.**, formerly known as Wal-Mart Stores, Inc., is a Delaware corporation with its principal place of business in Bentonville, Arkansas.

241. Defendant **WAL-MART STORES EAST, L.P.**, is a Delaware limited partnership with its principal place of business in Bentonville, Arkansas. , doing business as Wal-Mart Pharmacy Warehouse #46 and Wal-Mart Pharmacy Warehouse #45.

242. Walmart Inc. and Wal-Mart Stores East, L.P. are collectively referred to herein as (“Wal-Mart”).

243. Walmart, through its various DEA registrant subsidiaries and affiliated entities, conducts business as a licensed wholesale distributor.

244. At all times relevant to this Complaint, Walmart distributed prescription opioids throughout the United States, including in Cabell County and Huntington specifically.

245. During the relevant time period, and as further alleged below, Walmart entities also owned and operated pharmacies in Cabell County and Huntington West Virginia.

246. As a distributor of prescription opioids, Walmart distributes only to its own pharmacies.

247. Walmart pharmacies in Cabell County and Huntington, West Virginia also received distributions of prescription opioids from other Distributor Defendants.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

248. The volume of prescription opioids distributed to and dispensed by Walmart pharmacies in and around Huntington and Cabell County is indicative of diversion.

249. As a vertically integrated distributor and dispenser of prescription opioids, Walmart knew or should have known that an excessive volume of pills was being sold into Huntington and Cabell County, West Virginia.

250. Discovery will reveal that Wal-Mart knew or should have known that its pharmacies in the Tri-State area (West Virginia, Ohio, and Kentucky) were (a) filling multiple prescriptions to the same patient using the same doctor (b) filling multiple prescriptions by the same patient using different doctors (c) filling prescriptions of unusual size and frequency for the same patient (d) filling prescriptions of unusual size and frequency from out-of-state patients; (e) filling prescriptions of unusual size and frequency paid for in cash (f) filling prescriptions of unusual size and frequency from the same prescribing physician (g) filling prescriptions of unusual size and frequency from out-of-state physicians; and (h) filing prescriptions for patients and doctors in combinations that were indicative of diversion and abuse. Upon information and belief, the volumes of opioids distributed to and dispensed by these pharmacies were disproportionate to non-controlled drugs and other products sold by these pharmacies, and disproportionate to the sales of opioids in similarly sized pharmacy markets.

251. Walmart had complete access to, and full visibility of, all prescription opioid distribution data related Walmart pharmacies in and around Huntington and Cabell County, West Virginia.

252. Walmart had complete access to, and full visibility of, all prescription opioid dispensing data related Walmart pharmacies in and around Huntington and Cabell County, West Virginia.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

253. Walmart had complete access to information revealing the doctors who prescribed the prescription opioids dispensed in Walmart pharmacies in and around Huntington and Cabell County, West Virginia.

254. Walmart had complete access to information revealing the customers which filled (or sought to fill) prescriptions for opioids in Walmart pharmacies in and around Huntington and Cabell County, West Virginia.

255. Walmart had complete access to information revealing the opioids prescriptions dispensed by Walmart pharmacies in Huntington and Cabell County, West Virginia which were being paid for in cash.

256. Walmart had complete access to information revealing the geographic location of out-of-state doctors whose prescriptions for opioids were being filled in and around Huntington and Cabell County, West Virginia.

257. Walmart had complete access to information revealing the size and frequency of prescriptions written by specific doctors across their pharmacies in and around Huntington and Cabell County, West Virginia.

258. In addition to dispensing and distributing opioids, Walmart has marketed opioids during the relevant time period.

259. Defendants AmerisourceBergen, Cardinal, McKesson, H.D. Smith, CVS, Rite Aid, Walgreens, Kroger, and Wal-Mart are collectively referred to herein as "**Distributor Defendants**."

260. As set forth below, Defendants CVS, Rite Aid, Walgreens, Kroger, and Wal-Mart are also collectively referred to as **National Pharmacies**.⁶⁰

⁶⁰ Together, the Manufacturer or Marketing Defendants and Distributor Defendants are sometimes referred to as

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

261. Together, the Manufacturer or Marketing Defendants and Distributor Defendants are sometimes referred to as “**Supply Chain Defendants**.” Given that the National Pharmacy Defendants operated both as distributors and retail pharmacies, for purposes of this Complaint, “Distributor Defendants” is intended to include the National Pharmacy entities only in their capacities as distributors and “National Pharmacy Defendants” is intended to refer to the dispensing pharmacy entities unless stated otherwise.

C. National Pharmacies

262. The National Pharmacies operate as both distributors and retail pharmacies. At all relevant times, the National Pharmacies – in their capacities as distributors – distributed, supplied, sold, and placed prescription opioids into the stream of commerce, without fulfilling the fundamental duty of distributors to detect and warn of diversion of dangerous drugs.

263. In addition to their duties as distributors, the National Pharmacies also had a duty to design and implement systems to prevent diversion of controlled substances in their retail pharmacy operations. Specifically, the National Pharmacies had a duty to analyze chain wide data for known red flags such as (a) filling multiple prescriptions to the same patient using the same doctor; (b) filling multiple prescriptions by the same patient using different doctors; (c) filling orders of unusual size and frequency for the same patient (d) filling orders from out-of-state patients; (e) filling orders paid for in cash; (f) filling orders from the same prescribing physician; and (g) filling orders of unusual size and frequency from out-of-state physicians.

264. The National Pharmacies failed to fulfill these duties and instead, routinely dispensed controlled substances while ignoring the red flags of diversion and abuse. Plaintiff

“Supply Chain Defendants.” Given that the National Pharmacy Defendants operated both as distributors and retail pharmacies, for purposes of this Complaint, “Distributor Defendants” is intended to include the National Pharmacy entities only in their capacities as distributors and “National Pharmacy Defendants” is intended to refer to the dispensing pharmacy entities unless stated otherwise.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

alleges the unlawful conduct by the Dispensing Defendants is a substantial cause for the volume of prescription opioids plaguing Plaintiff's community.

1. CVS

265. As previously alleged, Defendant **CVS** owned and operated dispensing pharmacies in West Virginia, including in Cabell County and City of Huntington.

266. At all times relevant to this Complaint, CVS dispensed prescription opioids throughout the United States and in and around the City of Huntington and Cabell County, specifically.

267. As a DEA registered "dispenser" of prescription opioids, CVS owes a duty provide effective controls and procedures to guard against diversion of controlled substances.⁶¹

2. Rite Aid

268. As previously alleged, Defendant **Rite Aid** owned and operated dispensing pharmacies in West Virginia, including in Cabell County and City of Huntington.

269. At all times relevant to this Complaint, Rite Aid dispensed prescription opioids throughout the United States and in the City of Huntington, specifically.

270. As a DEA registered "dispenser" of prescription opioids, Rite Aid owes a duty provide effective controls and procedures to guard against diversion of controlled substances.⁶²

271. In addition to dispensing and distributing opioids, Rite Aid has marketed opioids during the relevant time period.

3. Walgreens

272. As previously alleged, Defendant **Walgreens** owned and operated dispensing pharmacies in West Virginia, including in Cabell County and City of Huntington.

⁶¹21 U.S.C. § 802(10); 21 U.S.C. § 822(a)(2)); and 21 C.F.R. § 1301.71.

⁶²21 U.S.C. § 802(10); 21 U.S.C. § 822(a)(2)); and 21 C.F.R. § 1301.71.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

273. At all times relevant to this Complaint, Walgreens dispensed prescription opioids throughout the United States and in the City of Huntington, specifically.

274. As a DEA registered “dispenser” of prescription opioids, Walgreens owes a duty provide effective controls and procedures to guard against diversion of controlled substances.⁶³

275. In addition to dispensing and distributing opioids, Walgreens has marketed opioids during the relevant time period.

4. Walmart

276. As previously alleged, Defendant **Walmart** owned and operated dispensing pharmacies in West Virginia, including in Cabell County and City of Huntington.

277. At all times relevant to this Complaint, Walmart dispensed prescription opioids throughout the United States and in the City of Huntington, specifically.

278. As a DEA registered “dispenser” of prescription opioids, Walmart owes a duty provide effective controls and procedures to guard against diversion of controlled substances.⁶⁴

279. In addition to dispensing and distributing opioids, Walmart has marketed opioids during the relevant time period.

5. Kroger

280. As previously alleged, Defendant **Kroger** owned and operated dispensing pharmacies in West Virginia, including in Cabell County and City of Huntington.

281. At all times relevant to this Complaint, Kroger dispensed prescription opioids throughout the United States and in the City of Huntington, specifically.

⁶³21 U.S.C. § 802(10); 21 U.S.C. § 822(a)(2)); and 21 C.F.R. § 1301.71.

⁶⁴21 U.S.C. § 802(10); 21 U.S.C. § 822(a)(2)); and 21 C.F.R. § 1301.71.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

282. As a DEA registered “dispenser” of prescription opioids, Kroger owes a duty provide effective controls and procedures to guard against diversion of controlled substances.⁶⁵

283. In addition to dispensing and distributing opioids, Kroger has marketed opioids during the relevant time period.

D. Pharmacy Benefit Managers

284. Pharmacy Benefit Managers (“PBMs”) administer benefit contracts and riders that determine coverage for some or all of the costs of pharmaceutical products and/or provide access to such products, sometimes through the PBM’s own mail-order pharmacy. PBMs establish formularies which govern which drugs are reimbursed and how. PBMs also determine pre-authorization requirements and negotiate with drug manufacturers to offer preferred drug formulary placement for drugs. Additionally, PBMs establish reimbursement rates for drugs dispensed and can earn revenue from fees from health plans and insurers, rebates and other incentives from drug manufacturers, including administrative fees and volume bonuses, and fees from maintaining pharmacy networks. Given their “gatekeeper” role, PBMs exercise significant power over the quantity of prescription opioids that enter the market.

285. PBMs also have massive quantities of data regarding the opioid prescribing and usage of the doctors and patients who participate in their plans. As a result, PBMs can identify: (a) patients who receive, and doctors who prescribe opioids in excessive volumes, frequency, or dosage; (b) patients who receive, and doctors who prescribe opioids in combination with other drugs indicative of diversion; (c) patients who receive opioids after having been treated or while being treated for opioid overdoses and addiction; and (d) patients who receive opioids who are at higher risk for overdose, for example, because they also receive benzodiazepines. This

⁶⁵21 U.S.C. § 802(10); 21 U.S.C. § 822(a)(2)); and 21 C.F.R. § 1301.71.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

information, and their representations about their efforts to manage and improve patients' health, created an obligation for PBMs to identify, report, and otherwise address potential diversion or other dangerous instances of opioid use and prescribing.

286. In addition, PBMs distribute opioids directly through their mail order pharmacies, and, like other pharmacies, are DEA registrants. In distributing opioids, PBMs are obligated to prevent diversion and to identify, report, and not ship suspicious orders of opioids. Upon information and belief, to be confirmed by transaction data in the exclusive possession of the PBMs, PBMs failed to carry out these duties.⁶⁶

1. Express Scripts

287. Defendant **EXPRESS SCRIPTS HOLDING COMPANY** ("ESHC") is a Delaware corporation with its principal place of business in St. Louis, Missouri. Defendant **Express Scripts, Inc.** ("ESI") is a wholly-owned subsidiary of ESHC and is incorporated in the State of Delaware with its principal place of business located in St. Louis, Missouri. In 2012, ESI acquired its rival, Medco Health Solutions Inc., otherwise known as Merck Medco, in a \$29.1 billion deal. As a result of the merger, ESHC was formed and became the largest PBM in the nation, filing a combined 1.4 billion prescriptions for employers and insurers.⁶⁷ ESHC and ESI are collectively referred to as "Express Scripts."

288. Express Scripts serves "100 million Americans" and describes itself as "making healthcare better, simpler and more affordable for patients, payers and providers."⁶⁸

⁶⁶ The ARCos data reported by PBMs track shipments only to PBM warehouses, and do not permit Plaintiffs to assess and identify potentially suspicious orders into Huntington and Cabell County.

⁶⁷ Peter Frost, *Express Scripts closes \$29.1-billion purchase of Medco*, LA Times (Apr. 3, 2012), <http://articles.latimes.com/2012/apr/03/business/la-fi-medco-20120403>

⁶⁸ Express Scripts, *Patient Outcomes: Our Measurement for Success*, available at <http://lab.express-scripts.com/lab/insights/industry-updates/patient-outcomes-our-measurement-for-success>.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

289. Upon information and belief, Express Scripts derived and continues to derive substantial revenue as a result of managing pharmacy benefits throughout West Virginia, including within Plaintiffs' Community.

2. CVS Caremark

290. Defendant **CAREMARK RX, LLC**, a Delaware limited liability company whose principal place of business is at the same location as CVS Health Corporation. Previously named Defendant **CVS Health Corporation**, is the parent company of Caremark Rx, LLC. Caremark Rx, LLC, in turn, is the parent company for many of CVS Health Corporations' mail order, pharmacy benefit management, and specialty mail and retail pharmacy subsidiaries.

291. Collectively, CVS Health Corporation, it its capacity as a pharmacy benefit manager, and Caremark Rx, LLC are referred to as "**CVS Caremark**."

292. CVS Caremark describes its PBM services as "help[ing] minimize client costs while improving health outcomes for more than 92 million plan members."⁶⁹ It also "operates four mail order pharmacies and offers broad capabilities that include formulary management and clinical services."⁷⁰

293. Upon information and belief, CVS Caremark derived and continues to derive substantial revenue as a result of managing pharmacy benefits throughout West Virginia, including within Plaintiffs' Community.

⁶⁹ CVS Health, *Pharmacy Benefits Management*, available at <https://cvshealth.com/about/our-offerings/pharmacy-benefits-management>.

⁷⁰ *Id.*

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

3. Optum Rx

294. Defendant, **OPTUM, INC.**, is a Delaware corporation with its principal place of business located in Eden Prairie, Minnesota. Optum, Inc. is a health services company managing the subsidiaries that administer UnitedHealth's pharmacy benefits, including OptumRx, Inc.

295. Defendant, OptumRx, Inc., is a Delaware corporation with its principal place of business located in Irvine, California. OptumRx operates as a subsidiary of OptumRx Holdings, LLC, which in turn operates as a subsidiary of Optum, Inc. Collectively, these entities are referred to as "Optum Rx."

296. Optum Rx describes itself as "helping clients and more than 65 million members achieve better health outcomes and lower overall costs through innovative prescription drug benefit services."

297. Upon information and belief, Optum Rx derived and continues to derive substantial revenue as a result of managing pharmacy benefits throughout West Virginia, including within Plaintiffs' Community.

298. Collectively, Defendants Express Scripts, CVS Caremark, and Optum Rx are referred to as the "**PBM Defendants.**"

299. Together, the PBM Defendants account for nearly 75 percent of the market of the national market.

E. Agency and Authority

300. All of the actions described in this Complaint are part of, and in furtherance of, the unlawful conduct alleged herein, and were authorized, ordered, and/or done by Defendants' officers, agents, employees, or other representatives while actively engaged in the management of Defendants' affairs within the course and scope of their duties and employment, and/or with Defendants' actual, apparent, and/or ostensible authority.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

JURISDICTION AND VENUE

301. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1331 because Plaintiff's claims under the Racketeer Influenced and Corrupt Organizations Act ("RICO"), 18 U.S.C. § 1961 *et seq.*, raise a federal question. This Court has supplemental jurisdiction over Plaintiff's state-law claims under 28 U.S.C. § 1337 because those claims are so related to the RICO claim as to form part of the same case or controversy.

302. This Court personal jurisdiction over each defendant as they conduct business in the State of West Virginia, where this action was originally filed, purposefully direct or directed their actions toward the State of West Virginia, some or all consented to be sued in the State of West Virginia by registering an agent for service of process, because they consensually submitted to the jurisdiction of the State West Virginia when obtaining a manufacturer or distributor license, and because they have the requisite minimum contacts with the State of West Virginia necessary to constitutionally permit the Court to exercise jurisdiction.

303. This Court also has personal jurisdiction over all of the defendants under 18 U.S.C. § 1965(b). This Court may exercise nation-wide jurisdiction over the named Defendants where the "ends of justice" require national service and Plaintiff demonstrates national contacts. Here, the interests of justice require that Plaintiff be allowed to bring the members of the nationwide RICO enterprise before the court in a single trial.

304. Venue as to each Defendant is proper in the Southern District of West Virginia under 28 U.S.C. § 1391(b)(2) because a substantial part of the events and omissions giving rise to the claim occurred in the Southern District of West Virginia.

305. Venue is also proper under 18 U.S.C. § 1965(a) because Defendants reside, are found, have agents, or transact their affairs in that district. On December 14, 2017, the Judicial

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

Panel on Multidistrict Litigation transferred this case to this Court for consolidated or coordinated pretrial proceedings.

306. The transferor court has personal jurisdiction over each defendant as they conduct business in the State of West Virginia, purposefully direct or directed their actions toward the State of West Virginia, some or all consented to be sued in the State of West Virginia by registering an agent for service of process, they consensually submitted to the jurisdiction of the State of West Virginia when obtaining a manufacturer or distributor license, and because they have the requisite minimum contacts with the State of West Virginia necessary to constitutionally permit the Court to exercise jurisdiction.

JURY DEMAND

307. Plaintiff demands a jury trial pursuant to Federal Rule of Civil Procedure

FACTUAL ALLEGATIONS

I. FACTS COMMON TO ALL CLAIMS⁷¹

A. Defendants' Conduct Created an Abatable Public Nuisance

308. As alleged throughout this Complaint, Defendants' conduct created a public health crisis and a public nuisance.

309. The public nuisance—i.e., the opioid epidemic—created, perpetuated, and maintained by Defendants can be abated and further recurrence of such harm and inconvenience can be abated by, *inter alia*, (a) educating prescribers (especially primary care physicians and the most prolific prescribers of opioids) and patients regarding the true risks and benefits of opioids, including the risk of addiction, in order to prevent the next cycle of addiction; (b) providing

⁷¹ The allegations in this complaint are made upon information and belief, including upon information immediately available to plaintiffs from the ARCos database upon their initial and intensive review. Plaintiffs reserve the right to seek leave to amend or correct this Complaint based upon further analysis of the ARCos, IMS, and other data and upon further investigation and discovery.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

addiction treatment to patients who are already addicted to opioids; and (c) making naloxone widely available so that overdoses are less frequently fatal.

310. Defendants have the ability to act to abate the public nuisance, and the law recognizes that they are uniquely well positioned to do so. It is the manufacturer of a drug that has primary responsibility to assure the safety, efficacy, and appropriateness of a drug's labeling, marketing, and promotion. And all companies in the supply chain of a controlled substance are primarily responsible for ensuring that such drugs are only distributed and dispensed to appropriate patients and not diverted. These responsibilities exist independent of any FDA or DEA regulation, to ensure that their products and practices meet both federal and state consumer protection laws and regulations. As registered manufacturers, distributors and dispensers of controlled substances, Defendants are placed in a position of special trust and responsibility and are uniquely positioned, based on their knowledge to act as a first line of defense.

B. Summary of the Origin of the Opioid Epidemic and Opioid Public Nuisance

311. This case arises from the worst man-made epidemic in modern medical history—the misuse, abuse, and over-prescription of opioids.⁷²

312. By now, most Americans have been affected, either directly or indirectly, by the opioid disaster. But few realize that this crisis arose from the opioid manufacturers,' distributors,' and dispensers deliberate efforts to evade restrictions. Manufacturers and distributors alike acted without regard for the lives that would be trammelled in pursuit of profit.

313. This drug crisis began with a corporate business plan. It started with a decision by Purdue and the Sackler Defendants (collectively, "Purdue Entities"), to promote opioids

⁷² As used herein, the term "opioid" refers to the entire family of opiate drugs including natural, synthetic and semi-synthetic opiates.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

deceptively and illegally in order to significantly increase sales and generate billions of dollars in revenue for Purdue's private owners, the Sackler family.

314. Purdue's strategies were quickly joined by other manufacturers, including Endo Health Solutions Inc.; Endo Pharmaceuticals, Inc.; Par Pharmaceutical, Inc.; Par Pharmaceutical Companies, Inc. f/k/a Par Pharmaceutical Holdings, Inc.; Janssen Pharmaceuticals, Inc.; Ortho-McNeil-Janssen Pharmaceuticals, Inc. n/k/a Janssen Pharmaceuticals, Inc.; Janssen Pharmaceutica, Inc. n/k/a Janssen Pharmaceuticals, Inc.; Johnson & Johnson; Noramco, Inc.; Teva Pharmaceutical Industries, Ltd.; Teva Pharmaceuticals USA, Inc.; Cephalon, Inc.; Mallinckrodt PLC; Mallinckrodt LLC; SpecGx LLC, Amneal, and KVK Tech (collectively the "Marketing Defendants").

315. Marketing Defendants manufacture, market, sell, and distribute branded and/or generic prescription opioid pain medications. Some of the relevant brand-name drugs include OxyContin, Butrans, Hysingla ER, Actiq, Fentora, Opana/Opana ER, Percodan, Percocet, Zydome, Nucynta/Nucynta ER, Duragesic, Exalgo, and Xartemis XR. The Marketing Defendants used misrepresentations regarding the risks and benefits of opioids to enable the widespread prescribing of opioids for common, chronic pain conditions like low back pain, arthritis, and headaches.⁷³

316. Prescription opioids are narcotics. They are derived from and possess properties similar to opium and heroin, and they are regulated as controlled substances. While opioids can dampen the perception of pain, they also can create an addictive, euphoric high. At higher doses, they can slow the user's breathing, causing potentially fatal respiratory depression. Most patients receiving more than a few weeks of opioid therapy will experience withdrawal symptoms if opioid use is delayed or discontinued —including severe anxiety, nausea, headaches, tremors, delirium,

⁷³ Consistent with the commonly accepted medical usage, the term "chronic pain" as used herein refers to non-cancer pain lasting three months or longer.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

and pain—which are often prolonged. When using opioids continuously, patients grow tolerant to their analgesic effects (i.e. to relief of pain)—requiring progressively higher doses and increasing the risks of withdrawal, addiction, and overdose.

317. Because the medical community recognized these dangers, they originally used opioids cautiously and sparingly, typically only for short-term acute pain—where brief use limited the need for escalating doses and the risk of addiction—or for palliative (end-of-life) care. Consequently, the market for prescription opioids was sharply constrained.

318. As Purdue developed OxyContin in the mid-1990s, it knew that to expand its market and profits, it needed to change the perception of opioids to permit and encourage the use of opioids long-term for widespread chronic conditions like back pain, migraines, and arthritis. Purdue, joined by the other Marketing Defendants began to promote opioids generally, and their own opioids in particular, as safe, effective, and appropriate for even long-term use for routine pain conditions. As part of this strategy, Defendants misrepresented the risk of addiction for pain patients as modest, manageable, and outweighed by the benefits of opioid use.

319. The Marketing Defendants' scheme was resoundingly successful. Chronic opioid therapy—the prescribing of opioids long-term to treat chronic pain—has become a commonplace, and often first-line, treatment. Marketing Defendants' deceptive marketing caused prescribing not only of their opioids, but of opioids as a class, to skyrocket. According to the CDC opioid prescriptions, as measured by number of prescriptions and morphine milligram equivalent ("MME") per person, tripled from 1999 to 2015. In 2015, on an average day, more than 650,000 opioid prescriptions were dispensed in the U.S. While previously a small minority of opioid sales, today between 80% and 90% of opioids (measured by weight) used are for chronic pain.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

320. Thus, rather than compassionately helping patients, this explosion in opioid use—and Defendants' profits—has come at the expense of chronic pain patients. As many as 1 in 4 patients who receive prescription opioids long-term for chronic pain in primary care settings struggles with addiction. Further, according to the CDC, one out of every 550 patients started on opioid therapy die of opioid-related causes a median of 2.6 years after their first opioid prescription.⁷⁴ That number increases to 1 in 32 for patients receiving 200 MMEs per day.⁷⁵ As the then CDC director concluded: “We know of no other medication routinely used for a nonfatal condition that kills patients so frequently.”⁷⁶

321. Studies have linked the increased marketing of opioids to abuse, addiction and death. “Areas in this country hardest hit by the prescription opioid crisis were the same areas targeted by drug companies marketing opioids,” said Scott Hadland, a pediatrician and researcher at the Grayken Center and also the lead author of a study linking marketing spends to opioids deaths.⁷⁷

322. Cabell County, West Virginia, for example, received 32 times more dollars in prescription opioid marketing than the national average. “Opioid manufacturers spent \$11,676 on marketing per every thousand residents living in the region at the foothills of the Appalachians” – approximately \$1,000 for each person. That money had an impact, Hadland said. Cabell County saw the most prescription opioid overdose deaths in the U.S. during the months surveyed.⁷⁸

⁷⁴ Thomas R. Frieden, M.D. and Debra Houry, M.D., *Reducing the Risks of Relief –The CDC Opioid-Prescribing Guideline* at 1503, NEJM, April 21, 2016.

⁷⁵ 90 MME is approximately 230 mg of OxyContin.

⁷⁶ CDC, Examining the Growing Problems of Prescription Drug and Heroin Abuse (Apr. 29, 2014), available at <http://www.cdc.give.washington/testify/2014/t20140429.htm>; Vivek H. Murthy, Letter from the Surgeon General, August 2016, available at <http://turnthetiderx.org>.

⁷⁷ Bloomberg, [Big Pharma Marketing Spending Tied to Opioid Deaths, Study Finds \(Jan. 23, 2009\)](#) available at <https://www.industryweek.com/companies-executives/big-pharma-marketing-spending-tied-opioid-deaths-study-finds>

⁷⁸ *Id.*

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

323. Once the Marketing Defendants, employing the help of Distributor Defendants, created a mass market for prescription opioids, McKesson Corporation, AmerisourceBergen Drug Corporation, Cardinal Health, Inc., H.D. Smith Wholesale Drug Co., CVS, Rite Aid, Walgreens, Kroger, and Wal-Mart, Inc. (together “Distributor Defendants”), along with Marketing Defendants, flooded it. Distributor Defendants are responsible for delivering opioids marketed and made by the Marketing Defendants to pharmacies and other customers throughout the country. Distributor Defendants have a duty under state law and federal law to report and to not ship suspicious orders of controlled substances into the Plaintiffs’ Community. Yet, Distributor and Marketing Defendants repeatedly shipped suspicious orders of opioids – often in quantities that they knew or should have known exceed any legitimate market for opioids, even the wider market for chronic pain, and ignored red flags of suspicious orders of these drugs in the Plaintiffs’ Communities, thereby exacerbating the oversupply of such drugs and fueling an illegal secondary market.

324. Other Defendants, like National Pharmacies and PBMs, deepened, expanded, and extended the overuse and oversupply of opioids. The National Pharmacies turned a blind eye to known red flags of diversion. The PBMs, in turn, exacerbated the flood by giving opioids preferential treatment and ensuring prescription opioids were given preferential treatment and covered by both public and private benefit plans throughout West Virginia and in Cabell County and the City of Huntington in particular.

325. As millions became addicted to opioids, “pill mills,” often styled as “pain clinics,” sprouted nationwide and rogue prescribers stepped in to supply prescriptions for non-medical use. These pill mills, typically under the auspices of licensed medical professionals, issue high volumes of opioid prescriptions under the guise of medical treatment. Pill mills in and around Huntington

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

and Cabell County, in neighboring states, and in Florida, directly supplied illicit opioids into Plaintiffs' Community. Prescription opioid pill mills and rogue prescribers would not have been able to channel opioids for illicit use without at least the tacit support and willful blindness of the Defendants, if not their knowing support.

C. Opioids and Their Effect

326. The term “opioid” refers to a class of drugs that bind with opioid receptors in the brain and includes natural, synthetic, and semi-synthetic opioids. Natural opioids are derived from the opium poppy. Generally used to treat pain, opioids produce multiple effects on the human body, the most significant of which are analgesia, euphoria, and respiratory depression.

327. The medicinal properties of opioids have been recognized for millennia—as well as their potential for abuse and addiction. The opium poppy contains various opium alkaloids, three of which are used in the pharmaceutical industry today: morphine, codeine, and thebaine. Early use of opium in Western medicine was with a tincture of opium and alcohol called laudanum, which contains all of the opium alkaloids and is still available by prescription today. Chemists first isolated the morphine and codeine alkaloids in the early 1800s.

328. In 1827, the pharmaceutical company Merck began large-scale production and commercial marketing of morphine. During the American Civil War, field medics commonly used morphine, laudanum, and opium pills to treat the wounded, and many veterans were left with morphine addictions. By 1900, an estimated 300,000 people were addicted to opioids in the United States, and many doctors prescribed opioids solely to prevent their patients from suffering withdrawal symptoms. The nation’s first Opium Commissioner, Hamilton Wright, remarked in 1911, “The habit has this nation in its grip to an astonishing extent. Our prisons and our hospitals are full of victims of it, it has robbed ten thousand businessmen of moral sense and made them

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

beasts who prey upon their fellows . . . it has become one of the most fertile causes of unhappiness and sin in the United States.”⁷⁹

329. Pharmaceutical companies tried to develop substitutes for opium and morphine that would provide the same analgesic effects without the addictive properties. In 1898, Bayer Pharmaceutical Company began marketing diacetylmorphine (obtained from acetylation of morphine) under the trade name “Heroin.” Bayer advertised heroin as a non-addictive cough and cold remedy suitable for children, but as its addictive nature became clear, heroin distribution in the U.S. was limited to prescription only in 1914 and then banned altogether a decade later.

330. Although heroin and opium became classified as illicit drugs, there is little difference between them and prescription opioids. Prescription opioids are synthesized from the same plant as heroin, have similar molecular structures, and bind to the same receptors in the human brain.

331. Due to concerns about their addictive properties, prescription opioids have usually been regulated at the federal level as Schedule II controlled substances by the U.S. Drug Enforcement Administration (“DEA”) since 1970.

332. Throughout the twentieth century, pharmaceutical companies continued to develop prescription opioids like Percodan, Percocet, and Vicodin, but these opioids were generally produced in combination with other drugs, with relatively low opioid content.

333. In contrast, OxyContin, the product whose launch in 1996 ushered in the modern opioid epidemic, is pure oxycodone. Purdue initially made it available in the following strengths: 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 60 mg, 80 mg, and 160 mg. The weakest OxyContin delivers

⁷⁹ Nick Miroff, *From Teddy Roosevelt to Trump: How Drug Companies Triggered an Opioid Crisis a Century Ago*, The Wash. Post (Oct. 17, 2017), https://www.washingtonpost.com/news/retropolis/wp/2017/09/29/the-greatest-drug-fiends-in-the-world-an-american-opioid-crisis-in-1908/?utm_term=.7832633fd7ca

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

as much narcotic as the strongest Percocet, and some OxyContin tablets delivered sixteen times that.

334. Medical professionals describe the strength of various opioids in terms of morphine milligram equivalents (“MME”). According to the CDC, doses at or above 50 MME/day double the risk of overdose compared to 20 MME/day, and one study found that patients who died of opioid overdose were prescribed an average of 98 MME/day.

335. Different opioids provide varying levels of MMEs. For example, just 33 mg of oxycodone provides 50 MME. Thus, at OxyContin’s twice-daily dosing, the 50 MME/day threshold is nearly reached by a prescription of 15 mg twice daily. One 160 mg tablet of OxyContin, which Purdue took off the market in 2001, delivered 240 MME.

336. The wide variation in the MME strength of prescription opioids renders misleading any effort to capture “market share” by the number of pills or prescriptions attributed to Purdue or other manufacturers. Purdue, in particular, focuses its business on branded, highly potent pills, causing it to be responsible for a significant percent of the total amount of MME in circulation, even though it currently claims to have a small percent of the market share in terms of pills or prescriptions.

337. Fentanyl is a synthetic opioid that is 100 times stronger than morphine and 50 times stronger than heroin. First developed in 1959, fentanyl is showing up more and more often in the market for opioids created by Marketing Defendants’ promotion, with particularly lethal consequences.

338. The effects of opioids vary by duration. Long-acting opioids, such as Purdue’s OxyContin and MS Contin, Janssen’s Nucynta ER and Duragesic, Endo’s Opana ER, and Actavis’s Kadian, are designed to be taken once or twice daily and are purported to provide

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

continuous opioid therapy for, in general, 12 hours. Short-acting opioids, such as Cephalon's Actiq and Fentora, are designed to be taken in addition to long-acting opioids to address "episodic pain" (also referred to as "breakthrough pain") and provide fast-acting, supplemental opioid therapy lasting approximately 4 to 6 hours. Still other short-term opioids, are designed to be taken in addition to long-acting opioids to specifically address breakthrough cancer pain, excruciating pain suffered by some patients with end-stage cancer. The Marketing Defendants promoted the idea that pain should be treated by taking long-acting opioids continuously and supplementing them by also taking short-acting, rapid-onset opioids for episodic or "breakthrough" pain.

339. Patients develop tolerance to the analgesic effect of opioids relatively quickly. As tolerance increases, a patient typically requires progressively higher doses in order to obtain the same perceived level of pain reduction. The same is true of the euphoric effects of opioids—the "high." However, opioids depress respiration, and at very high doses can and often do arrest respiration altogether. At higher doses, the effects of withdrawal are more severe. Long-term opioid use can also cause hyperalgesia, a heightened sensitivity to pain.

340. Discontinuing opioids after more than just a few weeks of therapy will cause most patients to experience withdrawal symptoms. These withdrawal symptoms include: severe anxiety, nausea, vomiting, headaches, agitation, insomnia, tremors, hallucinations, delirium, pain, and other serious symptoms, which may persist for months after a complete withdrawal from opioids, depending on how long the opioids were used.

D. The Resurgence of Opioid Use in the United States**1. The Sackler Family Integrated Advertising and Medicine**

341. Given the history of opioid abuse in the U.S. and the medical profession's resulting wariness, the commercial success of the Marketing Defendants' prescription opioids would not

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

have been possible without a fundamental shift in prescribers' perception of the risks and benefits of long-term opioid use.

342. As it turned out, Purdue Pharma was uniquely positioned to execute just such a maneuver, thanks to the legacy of a man named Arthur Sackler. The Sackler family is the sole owner of Purdue and one of the wealthiest families in America, with a net worth of \$13 billion as of 2016. The company's profits go to Sackler family trusts and entities. Yet the Sacklers have avoided publicly associating themselves with Purdue, letting others serve as the spokespeople for the company.

343. The Sackler brothers—Arthur, Mortimer, and Raymond—purchased a small patent-medicine company called the Purdue Frederick Company in 1952. It was Arthur Sackler who created the pharmaceutical advertising industry as we know it, laying the groundwork for the OxyContin promotion that would make the Sacklers billionaires.

344. Arthur Sackler was both a psychiatrist and a marketing executive. He pioneered both print advertising in medical journals and promotion through physician "education" in the form of seminars and continuing medical education courses. He also understood the persuasive power of recommendations from fellow physicians, and did not hesitate to manipulate information when necessary. For example, one promotional brochure produced by his firm for Pfizer showed business cards of physicians from various cities as if they were testimonials for the drug, but when a journalist tried to contact these doctors, he discovered that they did not exist.

345. It was Arthur Sackler who, in the 1960s, made Valium into the first \$100-million drug, so popular it became known as "Mother's Little Helper." When Arthur's client, Roche, developed Valium, it already had a similar drug, Librium, another benzodiazepine, on the market for treatment of anxiety. So Arthur invented a condition he called "psychic tension"—essentially

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

stress—and pitched Valium as the solution.⁸⁰ The campaign, for which Arthur was compensated based on volume of pills sold, was a remarkable success.

346. Arthur Sackler created not only the advertising for his clients but also the vehicle to bring their advertisements to doctors—a biweekly newspaper called the Medical Tribune, which was distributed for free to doctors nationwide. Arthur also conceived a company now called IMS Health Holdings Inc., which monitors prescribing practices of every doctor in the U.S. and sells this valuable data to pharmaceutical companies like Marketing Defendants, who utilize it to target and tailor their sales pitches to individual physicians.

2. Purdue and the Development of OxyContin

347. After the Sackler brothers acquired the Purdue Frederick Company in 1952, Purdue sold products ranging from earwax remover to antiseptic, and it became a profitable business. As an advertising executive, Arthur Sackler was not involved, on paper at least, in running Purdue. Raymond Sackler became Purdue’s head executive, while Mortimer Sackler ran Purdue’s UK affiliate.

348. In the 1980s, Purdue, through its UK affiliate, acquired a Scottish drug producer that had developed a sustained-release technology suitable for morphine. Purdue marketed this extended-release morphine as MS Contin, and it quickly became Purdue’s bestseller. As the patent expiration for MS Contin loomed, Purdue searched for a drug to replace it. Around that time, Raymond’s oldest son, Richard Sackler, who was also a trained physician, became more involved in the management of the company. Richard had grand ambitions for the company; according to a

⁸⁰ Barry Meier, *Pain Killer: A “Wonder” Drug’s Trail of Addiction and Death* 204 (Rodale 2003) (hereinafter “Meier”); see also *One Family Reaped Billions From Opioids*, WBUR On Point (Oct. 23, 2017), <https://www.statnews.com/2016/10/26/oxycontin-maker-thwarted-limits/>.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

long-time Purdue sales representative, “Richard really wanted Purdue to be big—I mean really big.”⁸¹ Richard believed Purdue should develop another use for its “Contin” timed-release system.

349. In 1990, Purdue’s vice president of clinical research, Robert Kaiko, sent a memo to Richard and other executives recommending that the company work on a pill containing oxycodone. At the time, oxycodone was perceived as less potent than morphine, largely because it was most commonly prescribed as Percocet, a relatively weak oxycodone-acetaminophen combination pill. MS Contin was not only approaching patent expiration but had always been limited by the stigma associated with morphine. Oxycodone did not have that problem, and what’s more, it was sometimes mistakenly called “oxycodine,” which also contributed to the perception of relatively lower potency, because codeine is weaker than morphine. Purdue acknowledged using this to its advantage when it later pled guilty to criminal charges of “misbranding” in 2007, admitting that it was “well aware of the incorrect view held by many physicians that oxycodone was weaker than morphine” and “did not want to do anything ‘to make physicians think that oxycodone was stronger or equal to morphine’ or to ‘take any steps . . . that would affect the unique position that OxyContin’” held among physicians.⁸²

350. For Purdue and OxyContin to be “*really* big,” Purdue needed to both distance its new product from the traditional view of narcotic addiction risk, and broaden the drug’s uses beyond cancer pain and hospice care. A marketing memo sent to Purdue’s top sales executives in March 1995 recommended that if Purdue could show that the risk of abuse was lower with OxyContin than with traditional immediate-release narcotics, sales would increase. As discussed

⁸¹ Christopher Glazek, *The Secretive Family Making Billions from the Opioid Crisis*, Esquire (Oct. 16, 2017), <http://www.esquire.com/news-politics/a12775932/sackler-family-oxycontin/>.

⁸² *Id.*

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

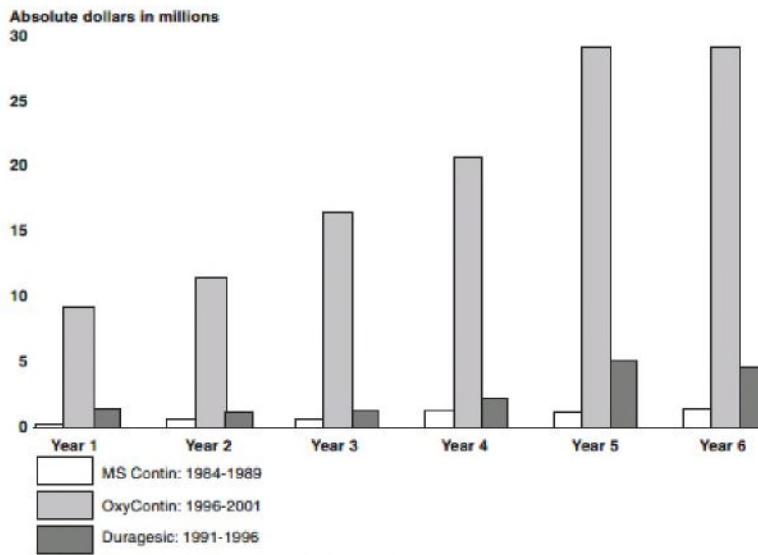
below, Purdue did not find or generate any such evidence, but this did not stop Purdue from making that claim regardless.

351. Armed with this and other misrepresentations about the risks and benefits of its new drug, Purdue was able to open an enormous untapped market: patients with non-end-of-life, non-acute, everyday aches and pains. As Dr. David Haddox, a Senior Medical Director at Purdue, declared on the Early Show, a CBS morning talk program, “There are 50 million patients in this country who have chronic pain that’s not being managed appropriately every single day. OxyContin is one of the choices that doctors have available to them to treat that.”⁸³

352. In pursuit of these 50 million potential customers, Purdue poured resources into OxyContin’s sales force and advertising, particularly to a far broader audience of primary care physicians who treated patients with chronic pain complaints. The graph below shows how promotional spending in the first six years following OxyContin’s launch dwarfed Purdue’s spending on MS Contin or Defendant Janssen’s spending on Duragesic.⁸⁴

⁸³ Meier, *supra*, at 156.

⁸⁴ U.S. General Accounting Office, *OxyContin Abuse and Diversion and Efforts to Address the Problem*, U.S. General Accounting Office Report to Congressional Requesters, at 22 (Dec. 2003), <http://www.gao.gov/new/items/d04110.pdf>.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER**Figure 1: Promotional Spending for Three Opioid Analgesics in First 6 Years of Sales**

Source: DEA and IMS Health, Integrated Promotional Service Audit.

Note: Dollars are 2002 adjusted.

353. Prior to Purdue's launch of OxyContin, no drug company had ever promoted such a pure, high-strength Schedule II narcotic to so wide an audience of general practitioners.

354. In the two decades following OxyContin's launch, Purdue continued to devote substantial resources to its promotional efforts.

355. Purdue has generated estimated sales of more than \$35 billion from opioids since 1996, raking in more than \$3 billion in 2015 alone. Remarkably, its opioid sales continued to climb even after a period of media attention and government inquiries regarding OxyContin abuse in the early 2000s and a criminal investigation culminating in guilty pleas in 2007. Purdue proved itself skilled at evading full responsibility and continuing to sell through the controversy. The company's annual opioid sales of \$3 billion in 2015 represent a four-fold increase from its 2006 sales of \$800 million.

356. One might imagine that Richard Sackler's ambitions have been realized. But in the best tradition of family patriarch Arthur Sackler, Purdue has its eyes on even greater profits. Under

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

the name of Mundipharma, the Sacklers are looking to new markets for their opioids—employing the exact same playbook in South America, China, and India as they did in the United States.

357. In May 2017, a dozen members of Congress sent a letter to the World Health Organization, warning it of the deceptive practices Purdue is unleashing on the rest of the world through Mundipharma:

We write to warn the international community of the deceptive and dangerous practices of Mundipharma International—an arm of Purdue Pharmaceuticals. The greed and recklessness of one company and its partners helped spark a public health crisis in the United States that will take generations to fully repair. We urge the World Health Organization (WHO) to do everything in its power to avoid allowing the same people to begin a worldwide opioid epidemic. Please learn from our experience and do not allow Mundipharma to carry on Purdue's deadly legacy on a global stage.

...

Internal documents revealed in court proceedings now tell us that since the early development of OxyContin, Purdue was aware of the high risk of addiction it carried. Combined with the misleading and aggressive marketing of the drug by its partner, Abbott Laboratories, Purdue began the opioid crisis that has devastated American communities since the end of the 1990s. Today, Mundipharma is using many of the same deceptive and reckless practices to sell OxyContin abroad. . . .

In response to the growing scrutiny and diminished U.S. sales, the Sacklers have simply moved on. On December 18, the Los Angeles Times published an extremely troubling report detailing how in spite of the scores of lawsuits against Purdue for its role in the U.S. opioid crisis, and tens of thousands of overdose deaths, Mundipharma now aggressively markets OxyContin internationally. In fact, Mundipharma uses many of the same tactics that caused the opioid epidemic to flourish in the U.S., though now in countries with far fewer resources to devote to the fallout.⁸⁵

358. Purdue's recent pivot to untapped markets—after extracting substantial profits from American communities and leaving local governments to address the devastating and still

⁸⁵ Letter from Members of Congress to Dr. Margaret Chan, Director-General, World Health Organization (May 3, 2017), http://katherineclark.house.gov/_cache/files/a577bd3c-29ec-4bb9-bdba-1ca71c784113/mundipharma-letter-signatures.pdf.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

growing damage the company caused—only serves to underscore that Purdue’s actions have been knowing, intentional, and motivated by profits throughout this entire story.

3. Other Marketing Defendants Leapt at the Opioid Opportunity

359. Purdue created a market for the use of opioids for a range of common aches and pains by misrepresenting the risks and benefits of its opioids, but it was far from alone. The other Marketing Defendants—already manufacturers of prescription opioids—positioned themselves to take advantage of the opportunity Purdue created, developing both branded and generic opioids to compete with OxyContin, while, together with Purdue and each other, misrepresenting the safety and efficacy of their products. These misrepresentations are described in greater detail below.

360. Endo, which already sold Percocet and Percodan, was the first to submit an application for a generic extended-release oxycodone to compete with OxyContin. At the same time, Endo sought FDA approval for another potent opioid, immediate-release and extended-release oxymorphone, branded as Opana and Opana ER. Oxymorphone, like OxyContin’s active ingredient oxycodone, is not a new drug; it was first synthesized in Germany in 1914 and sold in the U.S. by Endo beginning in 1959 under the trade name Numorphan. But Numorphan tablets proved highly susceptible to abuse. Called “blues” after the light blue color of the 10 mg pills, Numorphan provoked, according to some users, a more euphoric high than heroin. As the National Institute on Drug Abuse observed in its 1974 report, “Drugs and Addict Lifestyle,” Numorphan was extremely popular among addicts for its quick and sustained effect.⁸⁶ Endo withdrew oral Numorphan from the market in 1979.

361. Two decades later, however, as communities around the U.S. were first sounding the alarm about prescription opioids and Purdue executives were being called to testify before

⁸⁶ John Fauber and Kristina Fiore, *Abandoned Painkiller Makes a Comeback*, MedPage Today (May 10, 2015), <https://www.medpagetoday.com/psychiatry/addictions/51448>.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

Congress about the risks of OxyContin, Endo essentially reached back into its inventory, dusted off a product it had previously shelved after widespread abuse, and pushed it into the marketplace with a new trade name, Opana.

362. The clinical trials submitted with Endo's first application for approval of Opana were insufficient to demonstrate efficacy, and some subjects in the trials overdosed and had to be revived with naloxone. Endo then submitted new "enriched enrollment" clinical trials, in which trial subjects who do not respond to the drug are excluded from the trial, and obtained approval. Endo began marketing Opana and Opana ER in 2006.

363. Like Numorphan, Opana ER was highly susceptible to abuse. On June 8, 2017, the FDA sought removal of Opana ER. In its press release, the FDA indicated that "[t]his is the first time the agency has taken steps to remove a currently marketed opioid pain medication from sale due to the public health consequences of abuse."⁸⁷ On July 6, 2017, Endo agreed to withdraw Opana ER from the market. Janssen, which already marketed the Duragesic (fentanyl) patch for severe pain, also joined Purdue in pursuit of the broader chronic pain market. It sought to expand the use of Duragesic through, for example, advertisements proclaiming, "It's not just for end stage cancer anymore!" This claim earned Janssen a warning letter from the FDA, for representing that Duragesic was "more useful in a broader range of conditions or patients than has been demonstrated by substantial evidence."⁸⁸

364. Janssen also developed a new opioid compound called tapentadol in 2009, marketed as Nucynta for the treatment of moderate to severe pain. Janssen launched the extended-release version, Nucynta ER, for treatment of chronic pain in 2011.

⁸⁷ Press Release, U.S. Food & Drug Administration, *FDA requests removal of Opana ER for risks related to abuse* (June 8, 2017), <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm562401.htm>.

⁸⁸ March 30, 2000 FDA letter to Janssen.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

365. Not only did Janssen manufacture its own branded drugs, but also, its subsidiaries Tasmanian Alkaloids and Noramco were responsible for processing the active pharmaceutical ingredients (“API”) for other opioid manufacturers. As a result, Janssen profited from the growth of both unbranded and branded opioids and was driven to develop the market as much as possible.

366. Janssen had a global Active Pharmaceutical Ingredients (API) manufacturing network for opiate analgesics and antagonists. Noramco and Tasmanian Alkaloids were the primary suppliers of the active pharmaceutical ingredients provided to a number of opioid manufacturers. As stated above, eighty percent of Noramco’s sales were with all 7 of the top U.S. generic companies. Companies Noramco supplied included Teva, Endo, Purdue, Rhodes, Mallinckrodt, Actavis, Amneal and KVK . Noramco’s product portfolio includes Oxycodone (Oxycontin, Percocet, Roxicodone), Hydrocodone (Vicodin, Lortab), Morphine (MS Contin, Embeda).

367. In 1994, Janssen’s subsidiary, Tasmanian Alkaloids, established a research project “in order to develop a high thebaine poppy to meet the anticipated demand.” This project resulted in the development of the “Norman” poppy. It’s development “coincided with the release of a slow release formulation of oxycodone in the USA.”⁸⁹ The company reported:

- a. The new formulation was very successful, and there was greatly increased demand for the thebaine raw material used for its manufacture.
- b. This new poppy variety is a major turning point in alkaloid production.
- c. The high alkaloid content of the Tasmanian crop is our most important competitive advantage.
- d. Patented, high thebaine poppy was a transformational technology that enabled the growth of oxydodone.

⁸⁹ A.J. Fist, “The Tasmanian Poppy Industry: A Case Study of the Application of Science and Technology,” Tasmanian Alkaloids Pty. Ltd., Westbury, Tasmania.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

e. API volume growth linked to generics of branded drugs, new delivery systems & abuse prevention claims.

368. Noramco steadily gained in the U.S. market share reporting in 2014 alone that U.S. Sales of \$94MM for Oxycodone and \$52MM for Hydrocodone. In five years, from 2006 – 2011 their API volume growth doubled and continue climbing for the need for new capacity in 2015. Janssen's fully integrated supply chain provided security for continued growth.

369. Janssen fueled the opioid epidemic by providing a more potent poppy that could provide greater supply and/or profits. But, because of Noramco and Tasmanian Alkaloids, Janssen had an incentive to fraudulently market opioids with other Marketing Defendants as Janssen profited not only from its own opioid products, but from the sale of its API to other manufacturers.

370. Ironically, Janssen also profited from the rising addictions and abuse of opioids by supplying API for use in Naloxone for overdose and abuse, and in Naltrexone and Buprenorphine for opioid addiction.

371. By adding additional opioids or expanding the use of their existing opioid products, the other Marketing Defendants took advantage of the market created by Purdue's aggressive promotion of OxyContin and reaped enormous profits. For example, Opana ER alone generated more than \$1 billion in revenue for Endo in 2010 and again in 2013. Janssen also passed the \$1 billion mark in sales of Duragesic in 2009.

E. The Marketing Defendants' Multi-Pronged Scheme to Change Prescriber Habits and Public Perception and Increase Demand for Opioids

372. Until the mid-1990s, opioids were widely thought to be too addictive for use for chronic pain conditions, which would require long-term use of the drugs at increasingly high doses. For these conditions, the risks of addiction and other side effects outweighed any benefit from the drugs. Over the last two decades, Marketing Defendants turned that consensus on its head by

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

designing and implementing a sophisticated and deceptive market strategy that, among other things, falsely denied the risk of addiction and overstated the benefits of using opioids long-term.

373. Lacking legitimate scientific research to support their claims, Marketing Defendants turned to the marketing techniques first pioneered by Arthur Sackler to create a series of misperceptions in the medical community and ultimately reverse the long-settled understanding of the relative risks and benefits of opioids.

374. Through marketing that was as pervasive as it was deceptive, Marketing Defendants convinced health care providers both that the risks of long-term opioid use were overblown and that the benefits, in reduced pain and improved function and quality of life, were proven. Purdue, for example, promoted the concept that pain was undertreated, that opioids could not be abused, that the rate of addiction to opioids was less than 1%, that “old views” of opioid addiction were untrue, and that “appropriate patients” would not become addicted.

375. The result was that by the mid-2000s, the medical community had abandoned its prior caution, and opioids were entrenched as an appropriate—and often the first—treatment for chronic pain conditions. Marketing Defendants not only marketed opioids for chronic pain conditions, but also targeted primary care physicians (along with nurse practitioners and physician assistants),⁹⁰ who were most likely to see patients with chronic pain conditions and least likely to have the training and experience to evaluate Marketing Defendants’ marketing claims.

376. Marketing Defendants’ deceptive marketing created a cadre of doctors who looked for pain and treated it with opioids, which created an even broader cohort of patients who expected

⁹⁰ For example, in 2013, Purdue sought to identify Key Opinion Leaders (“KOLs”) to reach non-physician prescribers, including for a program to educate nurses about opioids. By 2015, nurse practitioners and physician assistants were responsible for over 800 million prescriptions and constituted Purdue’s largest growth area.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

and received opioids. This laid the groundwork for today's epidemic of opioid addiction, injury, and death.

377. The Marketing Defendants promoted, and profited from, their misrepresentations about the risks and benefits of opioids for chronic pain even though they knew that their marketing was false and misleading. The history of opioids, as well as research and clinical experience over the last 20 years, established that opioids were highly addictive and responsible for a long list of very serious adverse outcomes. The FDA and other regulators warned Marketing Defendants of these risks. The Marketing Defendants had access to scientific studies, detailed prescription data, and reports of adverse events, including reports of addiction, hospitalization, and deaths—all of which made clear the harms from long-term opioid use and that patients are suffering from addiction, overdoses, and death in alarming numbers. More recently, the FDA and CDC issued pronouncements based on existing medical evidence that conclusively expose the known falsity of these Defendants' misrepresentations.

378. The marketing scheme to increase opioid prescriptions centered around nine categories of misrepresentations, which are discussed in detail below. The Marketing Defendants disseminated these misrepresentations through various channels, including through advertising, sales representatives, purportedly independent organizations these defendants funded and controlled, “Front Groups,” so-called industry “Key Opinion Leaders,” and Continuing Medical Education (“CME”) programs discussed subsequently below.

1. The Marketing Defendants Promoted Multiple Falsehoods About Opioids

379. Marketing Defendants spent hundreds of millions of dollars on promotional activities and materials, including advertising, and websites that falsely denied or trivialized the risk of addiction and overstated the benefits of opioids. They also relied upon unsupported and

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

misleading information derived from seminars, treatment guidelines, and other publications and programs by patient advocacy groups, professional associations, and physicians that seemed independent and therefore credible, but were actually funded and controlled by Marketing Defendants.

380. For example, Purdue recruited and paid respected health care professionals as “speakers” who presented Purdue-approved programs to other prescribers at lunch and dinner events. From 1996 to 2001, Purdue held more than 40 national conferences and more than 5,000 physicians, pharmacist, and nurses attended these speaker conferences. In addition to speaker programs, Purdue targeted doctors with “educational” programing and funded more than 20,000 pain-related educational programs through direct sponsorship or financial grants by July 2002.

381. Marketing Defendants also used “key opinion leaders” (“KOLs”)—experts in the field who were especially influential because of their reputations and seeming objectivity—to deliver paid talks and continuing medical education programs (or “CMEs”) that provided information about treating pain and the risks, benefits, and use of opioids. These KOLs received substantial funding and research grants from the Marketing Defendants, and the CMEs were often sponsored by Defendants—giving them considerable influence over the messenger, the message, and the distribution of the program. Only doctors supportive of the use and safety of opioids for chronic pain received these funding and speaking opportunities, which were not only lucrative, but also helped doctors build their reputations and bodies of work. One notable KOL, Dr. Russell Portenoy, subsequently acknowledged that he gave lectures on opioids that reflected “misinformation” and were “clearly the wrong thing to do.”

382. In addition to talks and CMEs, these KOLs served on the boards of patient advocacy groups and professional associations, such as the American Pain Foundation and the American

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

Pain Society, which also took money directly from Marketing Defendants in an organized effort to exert greater influence because of their seeming independence. According to a report issued by the U.S. Senate Homeland Security & Governmental Affairs Committee, Ranking Member's Office, "many patient advocacy organizations and professional societies focusing on opioids policy have promoted messages and policies favorable to opioid use while receiving millions of dollars in payments from opioid manufacturers. Through criticism of government prescribing guidelines, minimization of opioid addiction risk, and other efforts, ostensibly neutral advocacy organizations have often supported industry interests at the expense of their own constituencies."⁹¹ These "front groups" for the opioid industry put out unbranded patient education materials and treatment guidelines that supported the use of opioids for chronic pain, overstated their benefits, and understated their risks. In many instances, Marketing Defendants distributed these publications to prescribers, including, upon information and belief, prescribers in the City, or posted them on their websites.

383. These third-party, unbranded materials were not reviewed or approved by the FDA. The FDA does not regulate all conduct engaged in by these Defendants. Marketing for chronic pain is not specifically approved. Medication labels do not address the use of opioids in treating specific conditions such as lower back pain, headaches, or fibromyalgia—three conditions for which opioids are not effective, but for which these Defendants marketed their drugs. Nor do the labels approve of the concept of "pseudoaddiction" or the technique of suggesting that abuse deterrent formulations are safer. In addition, though labels contain warnings about addiction, they do not quantify the severity of the risk. Marketing Defendants' asserted in branded and unbranded

⁹¹ U.S. S. Homeland Sec. & Governmental Aff. Comm., Ranking Members' Office, *Fueling an Epidemic*, Feb. 12, 2018, <https://www.hslc.org/?abstract&did=808171> at 3 (hereinafter, "Fueling an Epidemic").

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

marketing that screening, abuse deterrent formulations, or urinalysis could adequately manage the risk of developing an addiction without evidence to support these claims.

384. The Marketing Defendants' misrepresentations generally fall into the following nine categories:

1. The risk of addiction from chronic opioid therapy is low
2. Signs of addictive behavior are "pseudoaddiction," requiring more opioids
3. To the extent there is a risk of addiction, it can be easily identified and managed
4. Opioid withdrawal can be avoided by tapering
5. Long-term opioid use improves functioning
6. Opioid doses can be increased without limit or greater risks
7. Alternative forms of pain relief pose greater risks than opioids
8. OxyContin provides twelve hours of pain relief
9. New formulations of certain opioids successfully deter abuse

385. Each of these propositions was false. The Marketing Defendants knew this, but they nonetheless set out to convince physicians, patients, and the public at large of the truth of each of these propositions in order to expand the market for their opioids.

386. The categories of misrepresentations are offered to organize the numerous statements the Marketing Defendants made and to explain their role in the overall marketing effort, not as a checklist for assessing each Marketing Defendant's liability. While each Marketing Defendant deceptively promoted their opioids specifically, and, together with other Marketing Defendants, opioids generally, not every Marketing Defendant propagated (or needed to propagate) each misrepresentation. Each Marketing Defendant's conduct, and each misrepresentation, contributed to an overall narrative that aimed to—and did—mislead doctors,

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

patients, and payors about the risk and benefits of opioids. While this Complaint endeavors to document examples of each Marketing Defendant's misrepresentations and the manner in which they were disseminated, they are just that—examples. The Complaint is not, especially prior to discovery, an exhaustive catalog of the nature and manner of each deceptive statement by each Marketing Defendant.

387. Upon information and belief, all of the messages described below were disseminated to prescribers and patients in Plaintiffs' communities.

Falsehood #1: The risk of addiction from chronic opioid therapy is low

388. To convince prescribers and patients that opioids are safe, Marketing Defendants deceptively represented that the risk of abuse and addiction is modest and manageable and limited to illegitimate patients, not those with genuine pain. This created the dangerously misleading impressions that: (1) patients receiving opioid prescriptions for chronic pain would not become addicted, (2) patients at greatest risk of addiction could be identified, and (3) all other patients could safely be prescribed opioids.

389. Marketing Defendants undermined evidence that opioids are addictive by suggesting or stating that the risk of addiction is limited to high-risk patients. These Defendants also minimized the difficulty of withdrawal in their marketing material and promotional programs. For example, a 2011 non-credit educational program sponsored by Endo, entitled Persistent Pain in the Older Adult, claimed that withdrawal symptoms, which make it difficult for patients to stop using opioids, could be avoided by simply tapering a patient's opioid dose over ten days. However, this claim is at odds with the experience of patients addicted to opioids. Most patients who are dependent upon or addicted to opioids will experience withdrawal, characterized by intense physical and psychological effects, including anxiety, nausea, headaches, and delirium, among

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

others. This painful and arduous struggle to terminate use can leave many patients unwilling or unable to give up opioids and heightens the risk of addiction.

i. Purdue's misrepresentations regarding addiction risk

390. When it launched OxyContin, Purdue knew it would need data to overcome decades of wariness regarding opioid use. It needed some sort of research to back up its messaging. But Purdue had not conducted any studies about abuse potential or addiction risk as part of its application for FDA approval for OxyContin. Purdue (and, later, the other Defendants) found this “research” in the form of a one-paragraph letter to the editor published in the *New England Journal of Medicine* (NEJM) in 1980.

391. This letter, by Dr. Hershel Jick and Jane Porter, declared the incidence of addiction “rare” for patients treated with opioids.⁹² They had analyzed a database of hospitalized patients who were given opioids in a controlled setting to ease suffering from acute pain. Porter and Jick considered a patient not addicted if there was no sign of addiction noted in patients’ records.

⁹² Jane Porter and Herschel Jick, MD, *Addiction Rare in Patients Treated with Narcotics*, 302(2) N Engl J Med. 123 (Jan. 10, 1980), <http://www.nejm.org/doi/pdf/10.1056/NEJM198001103020221>.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

**ADDICTION RARE IN PATIENTS TREATED
WITH NARCOTICS**

To the Editor: Recently, we examined our current files to determine the incidence of narcotic addiction in 39,946 hospitalized medical patients¹ who were monitored consecutively. Although there were 11,882 patients who received at least one narcotic preparation, there were only four cases of reasonably well documented addiction in patients who had no history of addiction. The addiction was considered major in only one instance. The drugs implicated were meperidine in two patients,² Percodan in one, and hydromorphone in one. We conclude that despite widespread use of narcotic drugs in hospitals, the development of addiction is rare in medical patients with no history of addiction.

JANE PORTER
HERSHEL JICK, M.D.
Boston Collaborative Drug
Surveillance Program
Boston University Medical Center

Waltham, MA 02154

1. Jick H, Miettinen OS, Shapiro S, Lewis GP, Siskind Y, Slone D. Comprehensive drug surveillance. *JAMA*. 1970; 213:1455-60.
2. Miller RR, Jick H. Clinical effects of meperidine in hospitalized medical patients. *J Clin Pharmacol*. 1978; 18:180-8.

392. As Dr. Jick explained to a journalist years later, he submitted the statistics to NEJM as a letter because the data were not robust enough to be published as a study.⁹³

393. Purdue nonetheless began repeatedly citing this letter in promotional and educational materials as evidence of the low risk of addiction, while failing to disclose that its source was a letter to the editor, not a peer-reviewed paper.⁹⁴ Citation of the letter, which was largely ignored for more than a decade, significantly increased after the introduction of OxyContin. While first Purdue and then other Marketing Defendants used it to assert that their opioids were not addictive, “that’s not in any shape or form what we suggested in our letter,” according to Dr. Jick.

394. Purdue specifically used the Porter and Jick letter in its 1998 promotional video, “I got my life back,” in which Dr. Alan Spanos says, “In fact, the rate of addiction amongst pain patients who are treated by doctors *is much less than 1%*.⁹⁵ Purdue trained its sales

⁹³ Meier at 174.

⁹⁴ J. Porter & H. Jick, Addiction Rare in Patients Treated with Narcotics, 302(2) New. Eng. J. Med. 123 (1980).

⁹⁵ Our Amazing World, *Purdue Pharma OxyContin Commercial*, <https://www.youtube.com/watch?v=Er78Dj5hyel>

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

representatives to tell prescribers that fewer than 1% of patients who took OxyContin became addicted. (In 1999, a Purdue-funded study of patients who used OxyContin for headaches found that the addiction rate was thirteen per cent.)⁹⁶

395. Other Defendants relied on and disseminated the same distorted messaging. The enormous impact of Defendants' misleading amplification of this letter was well documented in another letter published in the NEJM on June 1, 2017, describing the way the one-paragraph 1980 letter had been irresponsibly cited and in some cases "grossly misrepresented." In particular, the authors of this letter explained:

[W]e found that a five-sentence letter published in the *Journal* in 1980 was heavily and uncritically cited as evidence that addiction was rare with long-term opioid therapy. We believe that this citation pattern contributed to the North American opioid crisis by helping to shape a narrative that allayed prescribers' concerns about the risk of addiction associated with long-term opioid therapy . . .⁹⁷

396. "It's difficult to overstate the role of this letter," said Dr. David Juurlink of the University of Toronto, who led the analysis. "It was the key bit of literature that helped the opiate manufacturers convince front-line doctors that addiction is not a concern."⁹⁸

397. Alongside its use of the Porter and Jick letter, Purdue also crafted its own materials and spread its deceptive message through numerous additional channels. In its 1996 press release announcing the release of OxyContin, for example, Purdue declared, "The fear of addiction is exaggerated."⁹⁹

(last visited Jan. 31, 2018) (emphasis added).

⁹⁶ Patrick Radden Keefe, *The Family That Built an Empire of Pain*, New Yorker (Oct. 30, 2017).

⁹⁷ Pamela T.M. Leung, B.Sc. Pharm., Erin M. Macdonald, M.Sc., Matthew B. Stanbrook, M.D., Ph.D., Irfan Al Dhalla, M.D., David N. Juurlink, M.D., Ph.D., *A 1980 Letter on the Risk of Opioid Addiction*, 376 N Engl J Med 2194-95 (June 1, 2017), <http://www.nejm.org/doi/full/10.1056/NEJMc1700150#t=article>.

⁹⁸ *Painful words: How a 1980 letter fueled the opioid epidemic*, STAT (May 31, 2017), <https://www.statnews.com/2017/05/31/opioid-epidemic-nejm-letter/>.

⁹⁹ Press Release, OxyContin, *New Hope for Millions of Americans Suffering from Persistent Pain: Long-Acting OxyContin Tablets Now Available to Relieve Pain* (May 31, 1996, 3:47pm), <http://documents.latimes.com/oxycontin-press-release-1996/>.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

398. At a hearing before the House of Representatives' Subcommittee on Oversight and Investigations of the Committee on Energy and Commerce in August 2001, Purdue emphasized "legitimate" treatment, dismissing cases of overdose and death as something that would not befall "legitimate" patients: "Virtually all of these reports involve people who are abusing the medication, not patients with legitimate medical needs under the treatment of a healthcare professional."¹⁰⁰

399. Purdue spun this baseless "legitimate use" distinction out even further in a patient brochure about OxyContin, called "A Guide to Your New Pain Medicine and How to Become a Partner Against Pain." In response to the question "Aren't opioid pain medications like OxyContin Tablets 'addicting'?", Purdue claimed that there was no need to worry about addiction if taking opioids for legitimate, "medical" purposes:

Drug addiction means using a drug to get "high" rather than to relieve pain. You are taking opioid pain medication for medical purposes. The medical purposes are clear and the effects are beneficial, not harmful.

400. Sales representatives marketed OxyContin as a product "to start with and to stay with."¹⁰¹ Sales representatives also received training in overcoming doctors' concerns about addiction with talking points they knew to be untrue about the drug's abuse potential. One of Purdue's early training memos compared doctor visits to "firing at a target," declaring that "[a]s you prepare to fire your 'message,' you need to know where to aim and what you want to hit!"¹⁰²

¹⁰⁰ *OxyContin: Its Use and Abuse: Hearing Before the H. Subcomm. on Oversight and Investigations of the Comm. on Energy and Commerce*, 107th Cong. 1 (Aug. 28, 2001) (statement of Michael Friedman, Executive Vice President, Chief Operating Officer, Purdue Pharma, L.P.), <https://www.gpo.gov/fdsys/pkg/CHRG-107hrg75754/html/CHRG-107hrg75754.htm>.

¹⁰¹ Keefe, *Empire Of Pain*.

¹⁰² Meier, *Pain Killer*, at 102.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

According to the memo, the target is physician resistance based on concern about addiction: “The physician wants pain relief for these patients without addicting them to an opioid.”¹⁰³

401. Purdue, through its unbranded website *Partners Against Pain*,¹⁰⁴ stated the following: “Current Myth: Opioid addiction (psychological dependence) is an important clinical problem in patients with moderate to severe pain treated with opioids. Fact: Fears about psychological dependence are exaggerated when treating appropriate pain patients with opioids.” “Addiction risk also appears to be low when opioids are dosed properly for chronic, noncancer pain.”

402. Former sales representative Steven May, who worked for Purdue from 1999 to 2005, explained to a journalist how he and his coworkers were trained to overcome doctors’ objections to prescribing opioids. The most common objection he heard about prescribing OxyContin was that “it’s just too addictive.”¹⁰⁵ May and his coworkers were trained to “refocus” doctors on “legitimate” pain patients, and to represent that “legitimate” patients would not become addicted. In addition, they were trained to say that the 12-hour dosing made the extended-release opioids less “habit-forming” than painkillers than need to be taken every four hours.

403. According to interviews with prescribers and former Purdue sales representatives, Purdue has continued to distort or omit the risk of addiction while failing to correct its earlier

¹⁰³ *Id.*

¹⁰⁴ *Partners Against Pain* consists of both a website, styled as an “advocacy community” for better pain care, and a set of medical education resources distributed to prescribers by sales representatives. It has existed since at least the early 2000s and has been a vehicle for Purdue to downplay the risks of addiction from long-term opioid use. One early pamphlet, for example, answered concerns about OxyContin’s addictiveness by claiming: “Drug addiction means using a drug to get ‘high’ rather than to relieve pain. You are taking opioid pain medication for medical purposes. The medical purposes are clear and the effects are beneficial, not harmful.”

¹⁰⁵ David Remnick, *How OxyContin Was Sold to the Masses* (Steven May interview with Patrick Radden Keefe), The New Yorker (Oct. 27, 2017), <https://www.newyorker.com/podcast/the-new-yorker-radio-hour/how-oxycontin-was-sold-to-the-masses>.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

misrepresentations, leaving many doctors with the false impression that pain patients will only rarely become addicted to opioids.

404. With regard to addiction, Purdue’s label for OxyContin has not sufficiently disclosed the true risks to, and experiences of, its patients. Until 2014, the OxyContin label stated in a black-box warning that opioids have “abuse potential” and that the “risk of abuse is increased in patients with a personal or family history of substance abuse.”

405. However, the FDA made clear to Purdue as early as 2001 that the disclosures in its OxyContin label were insufficient. Senior FDA officials met with Purdue on April 23, 2001, to “provide comments and suggestions on a Risk Management program for OxyContin. “Among other issues, the FDA noted that Purdue should add a black-box warning for overdose, abuse, and death to OxyContin’s label. Purdue acknowledged that it was aware of abuse of OxyContin orally (without tampering), as well as by snorting or injecting. It was not, the FDA explained, a matter of changing a few words in OxyContin’s label; Dr. Cynthia McCormick, then director of the FDA division overseeing pain medication, declared that “‘major overhaul is my message.’ The prescribing of OxyContin is creeping into a whole population of people where it doesn’t belong. Just rewriting the abuse and dependence section won’t help much, that part of the insert is not a pivot point.”

406. Another FDA participant asked that Purdue “refocus our promotional materials and make the risks of abuse and diversion more prominent.” In short, the FDA advised Purdue “that the information put in the label back at the time of product approval did not adequately address the risks associated with this product and this needs to be corrected.”

407. In 2001, Purdue revised the indication and warnings for OxyContin, but did not go nearly as far as the FDA recommended or the known risks of the product demanded. In the United

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

States, Purdue ceased distributing the 160 mg tablet of OxyContin. While Purdue agreed to “consider” changes to its label, it also expressed a reluctance to make significant changes not required for other prescription opioids. Dr. McCormick noted that the issues discussed at the meeting were specific to OxyContin and that, while the Agency would talk with Purdue’s competitors, “‘we have a problem here and now with OxyContin.’ In due time other manufacturers will be contacted but the first problem is this product.”

408. In the end, Purdue narrowed the recommended use of OxyContin to situations when “a continuous, around-the-clock analgesic is needed for an extended period of time” and added a warning that “[t]aking broken, chewed, or crushed OxyContin tablets” could lead to a “potentially fatal dose.” However, Purdue did not, until 2014, change the label as the FDA suggested, to indicate that OxyContin should not be the first therapy, or even the first opioid, used, and did not disclose the incidence or risk of overdose and death even when OxyContin was not abused. Purdue announced the label changes in a letter to health care providers but did not, as the FDA suggested, issue “a Medguide for patients on the risks of overdose and the abuse of opioids as well as risks for use by others than those for whom it was prescribed” or undertake the recommended promotional effort to educate patients about the potentially fatal risks of OxyContin.

409. The FDA also informed Purdue what Purdue already knew, as noted above—that “there is a perception that oxycodone is safer than morphine.” A representative from the FDA’s Division of Drug Marketing, Advertising and Communications echoed this, calling for an “extensive educational effort to consumers and health care practitioners” to “correct a misconception that [OxyContin] is different than morphine.” Upon information and belief, Purdue never undertook that effort.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

410. Purdue also heavily promoted the Joint Commission on Accreditation of Healthcare Organization's Pain as a Fifth Vital Sign, which encouraged health care providers to ask about pain and, presumably, to treat it with opioids. Purdue obtained exclusive rights to distribute Pain as a Fifth Vital Sign, and made sure that this guide, intended initially for hospital patients, was widely disseminated. Front groups supported by Marketing Defendants, particularly the University of Wisconsin Pain and Policy Study Group (PPSG), proposed the concept of Pain as a Fifth Vital Sign, which the review committee of outside physicians charged with evaluating guidelines rejected precisely because of their concern that it would result in overuse of opioids and increased addiction and overdose. JACHO nonetheless adopted by guidelines, presumably at the behest of PPSG and its supporters.

ii. Endo's misrepresentations regarding addiction risk

411. Endo also falsely represented that addiction is rare in patients who are prescribed opioids.

412. Until April 2012, Endo's website for Opana, www.opana.com, stated that “[m]ost healthcare providers who treat patients with pain agree that patients treated with prolonged opioid medicines usually do not become addicted.”

413. Upon information and belief, Endo improperly instructed its sales representatives to diminish and distort the risk of addiction associated with Opana ER. Endo's training materials for its sales representatives in 2011 also prompted sales representatives to answer “true” to the statement that addiction to opioids is not common.

414. One of the Front Groups with which Endo worked most closely was the American Pain Foundation (“APF”), described more fully below. Endo provided substantial assistance to, and exercised editorial control, over the deceptive and misleading messages that APF conveyed

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

through its National Initiative on Pain Control (“NIPC”)¹⁰⁶ and its website *Painknowledge.com*, which claimed that “[p]eople who take opioids as prescribed usually do not become addicted.”

415. Another Endo website, *PainAction.com*, stated: “Did you know? Most chronic pain patients do not become addicted to the opioid medications that are prescribed for them.”

416. A brochure available on *Painknowledge.com* titled “*Pain: Opioid Facts*,” Endo-sponsored NIPC stated that “people who have no history of drug abuse, including tobacco, and use their opioid medication as directed will probably not become addicted.”¹⁰⁷ In numerous patient education pamphlets, Endo repeated this deceptive message.

- In a patient education pamphlet titled “*Understanding Your Pain: Taking Oral Opioid Analgesics*,” Endo answers the hypothetical patient question—“What should I know about opioids and addiction?”—by focusing on explaining what addiction is (“a chronic brain disease”) and is not (“Taking opioids for pain relief”). It goes on to explain that “[a]ddicts take opioids for other reasons, such as unbearable emotional problems. Taking opioids as prescribed for pain relief is not addiction.” This publication is still available online.

417. An Endo publication, *Living with Someone with Chronic Pain*, stated, “Most health care providers who treat people with pain agree that most people do not develop an addiction problem.” A similar statement appeared on the Endo website, www.opana.com, until at least April 2012.

418. In addition, a 2009 patient education publication, *Pain: Opioid Therapy*, funded by Endo and posted on *Painknowledge.com*, omitted addiction from the “common risks” of opioids, as shown below:

¹⁰⁶ Endo was one of the APF’s biggest financial supporters, providing more than half of the \$10 million APF received from opioid manufacturers during its lifespan. Endo was the sole funder of NIPC and selected APF to manage NIPC. Internal Endo documents indicate that Endo was responsible for NIPC curriculum development, web posting, and workshops, developed and reviewed NIPC content, and took a substantial role in distributing NIPC and APF materials. Endo projected that it would be able to reach tens of thousands of prescribers nationwide through the distribution of NIPC materials.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

As with any medication, there are some side effects that are associated with opioid therapy. The most common side effects that occur with opioid use include the following:

- ▶ Constipation
- ▶ Drowsiness
- ▶ Confusion
- ▶ Nausea
- ▶ Itching
- ▶ Dizziness
- ▶ Shortness of breath

Your healthcare provider can help to address and, in some cases, prevent side effects that may occur as a result of opioid treatment. Less severe side effects, including nausea, itching, or drowsiness, typically go away within a few days without the need for further treatment. If you experience any side effects, you should let your healthcare provider know immediately.

iii. Janssen's misrepresentations regarding addiction risk

419. Janssen likewise misrepresented the addiction risk of opioids on its websites and print materials. One website, *Let's Talk Pain*, states, among other things, that “the stigma of drug addiction and abuse” associated with the use of opioids stemmed from a “lack of understanding about addiction.” (Although Janssen described the website internally as an unbranded third-party program, it carried Janssen’s trademark and copy approved by Janssen.)

420. The *Let's Talk Pain* website also perpetuated the concept of pseudoaddiction, associating patient behaviors such as “drug seeking,” “clock watching,” and “even illicit drug use or deception” with undertreated pain which can be resolved with “effective pain management.” In August 2009, a “12 month review” of the *Let's Talk Pain* website manuscript confirmed that the website’s contents included statements regarding pseudoaddiction and illustrated Janssen’s control over the website and awareness of its contents.

421. A Janssen unbranded website, *PrescribeResponsibly.com*, states that concerns about opioid addiction are “overestimated” and that “true addiction occurs only in a small percentage of patients.”¹⁰⁸

¹⁰⁸ Keith Candiotti, M.D., *Use of Opioid Analgesics in Pain Management*, Prescribe Responsibly, <http://www.prescriberesponsibly.com/articles/opioid-pain-management> (last modified July 2, 2015).

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

422. Janssen reviewed, edited, approved, and distributed a patient education guide entitled *Finding Relief: Pain Management for Older Adults*, which, as seen below, described as “myth” the claim that opioids are addictive, and asserted as fact that “[m]any studies show that opioids are rarely addictive when used properly for the management of chronic pain.” Until recently, this guide was still available online.

Opioid myths

Myth: Opioid medications are always addictive.

Fact: Many studies show that opioids are *rarely* addictive when used properly for the management of chronic pain.

423. Janssen’s website for Duragesic included a section addressing “Your Right to Pain Relief” and a hypothetical patient’s fear that “I’m afraid I’ll become a drug addict.” The website’s response: “Addiction is relatively rare when patients take opioids appropriately.”

424. According to an internal marketing assessment, Janssen sales representatives were trained to emphasize that Nucynta ER had fewer side effects than other opioids, though, upon information and belief, this was an untrue and unsubstantiated superiority claim.

425. Janssen also conducted a research study on prescribers regarding the visual aids for the marketing of Nucynta ER. Doctors reportedly were interested that Nucynta was described as appropriate for patients at risk for addiction and to avoid addictive narcotics for young people. Additionally, doctors identified the advantages of Nucynta, which included that it was potentially less addicting than other opioids and had a lower street value.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

426. Janssen also published a patient guide, *Patient Booklet Answers to Your Questions – Duragesic*, which stated that “Addiction is relatively rare when patients take opioids appropriately.”

427. Janssen recognized that this misrepresentation was particularly important to payors, who had a “negative” reaction to covering an addictive drug for a chronic condition for which non-narcotic drugs were available.

iv. Cephalon’s misrepresentations regarding addiction risk

428. Cephalon sponsored and facilitated the development of a guidebook, *Opioid Medications and REMS: A Patient’s Guide*, which included claims that “patients without a history of abuse or a family history of abuse do not commonly become addicted to opioids.” Similarly, Cephalon sponsored APF’s *Treatment Options: A Guide for People Living with Pain* (2007), which taught that addiction is rare and limited to extreme cases of unauthorized dose escalations, obtaining opioids from multiple sources, or theft.

429. For example, a 2003 Cephalon-sponsored CME presentation titled *Pharmacologic Management of Breakthrough or Incident Pain*, posted on Medscape in February 2003, teaches:

[C]hronic pain is often undertreated, particularly in the noncancer patient population. . . . The continued stigmatization of opioids and their prescription, coupled with often unfounded and self-imposed physician fear of dealing with the highly regulated distribution system for opioid analgesics, remains a barrier to effective pain management and must be addressed. Clinicians intimately involved with the treatment of patients with chronic pain recognize that the majority of suffering patients lack interest in substance abuse. In fact, patient fears of developing substance abuse behaviors such as addiction often lead to undertreatment of pain. The concern about patients with chronic pain becoming addicted to opioids during long-term opioid therapy may stem from confusion between physical dependence (tolerance) and psychological dependence (addiction) that manifests as drug abuse.¹⁰⁹

¹⁰⁹ Michael J. Brennan, et al., Pharmacologic Management of Breakthrough or Incident Pain, Medscape, <http://www.medscape.org/viewarticle/449803> (last visited Oct. 10, 2017).

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

430. An internal “educational” document claimed that “in patients without personal or family history of substance abuse, addiction resulting from exposure to opioid therapy is uncommon.” The document continued, “Like patients, caregivers may need reassurance that few people using opioids for a legitimate medical reason become addicted to the drug, and that physical dependence to a drug is easily overcome through scheduled dosing decreases . . . ” Upon information and belief, this Cephalon “learning module” was used to train sales representatives for their interactions with prescribers.

v. Actavis’s misrepresentations regarding addiction risk

431. Through its “Learn More about customized pain control with Kadian” material, Actavis claimed that it is possible to become addicted to morphine-based drugs like Kadian, but that it is “less likely” to happen in those who “have never had an addiction problem.” The piece goes on to advise that a need for a “dose adjustment” is the result of tolerance, and “not addiction.”

432. Training for Actavis sales representatives deceptively minimizes the risk of addiction by: (i) attributing addiction to “predisposing factors” like family history of addiction or psychiatric disorders; (ii) repeatedly emphasizing the difference between substance dependence and substance abuse; and (iii) using the term pseudoaddiction, which, as described below, dismisses evidence of addiction as the undertreatment of pain and, dangerously, counsels doctors to respond to its signs with more opioids.

433. Actavis conducted a market study on takeaways from prescribers’ interactions with Kadian sales representatives. The doctors had a strong recollection of the sales representatives’ discussion of the low-abuse potential. Actavis’ sales representatives’ misstatements on the low-abuse potential was considered an important factor to doctors, and was most likely repeated and reinforced to their patients. Additionally, doctors reviewed visual aids that the Kadian sales representatives use during the visits, and Actavis noted that doctors associate Kadian with less

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

abuse and no highs, in comparison to other opioids. Numerous marketing surveys of doctors in 2010 and 2012, for example, confirmed Actavis's messaging about Kadian's purported low addiction potential, and that it had less abuse potential than other similar opioids.

434. A guide for prescribers under Actavis's copyright deceptively represents that Kadian is more difficult to abuse and less addictive than other opioids. The guide includes the following statements: 1) "unique pharmaceutical formulation of KADIAN may offer some protection from extraction of morphine sulfate for intravenous use by illicit users," and 2) KADIAN may be less likely to be abused by health care providers and illicit users" because of "Slow onset of action," "Lower peak plasma morphine levels than equivalent doses of other formulations of morphine," "Long duration of action," and "Minimal fluctuations in peak to trough plasma levels of morphine at steady state." These statements convey both that (1) Kadian does not cause euphoria and therefore is less addictive and that (2) Kadian is less prone to tampering and abuse, even though Kadian was not approved by the FDA as abuse deterrent, and, upon information and belief, Actavis had no studies to suggest it was.

vi. Mallinckrodt's misrepresentations regarding addiction risk

435. As described below, Mallinckrodt promoted its branded opioids Exalgo and Xartemis XR, and opioids generally, in a campaign that consistently mischaracterized the risk of addiction. Mallinckrodt did so through its website and sales force, as well as through unbranded communications distributed through the "C.A.R.E.S. Alliance" it created and led.

436. Mallinckrodt in 2010 created the C.A.R.E.S. (Collaborating and Acting Responsibly to Ensure Safety) Alliance, which it describes as "a coalition of national patient safety, provider and drug diversion organizations that are focused on reducing opioid pain medication abuse and increasing responsible prescribing habits." The "C.A.R.E.S. Alliance" itself is a service mark of Mallinckrodt LLC (and was previously a service mark of Mallinckrodt, Inc.)

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

copyrighted and registered as a trademark by Covidien, its former parent company. Materials distributed by the C.A.R.E.S. Alliance, however, include unbranded publications that do not disclose a link to Mallinckrodt.

437. By 2012, Mallinckrodt, through the C.A.R.E.S. Alliance, was promoting a book titled *Defeat Chronic Pain Now!* This book is still available online. The false claims and misrepresentations in this book include the following statements:

- “Only rarely does opioid medication cause a true addiction when prescribed appropriately to a chronic pain patient who does not have a prior history of addiction.”
- “It is currently recommended that every chronic pain patient suffering from moderate to severe pain be viewed as a potential candidate for opioid therapy.”
- “When chronic pain patients take opioids to treat their pain, they rarely develop a true addiction and drug craving.”
- “Only a minority of chronic pain patients who are taking long-term opioids develop tolerance.”
- “**The bottom line:** Only rarely does opioid medication cause a true addiction when prescribed appropriately to a chronic pain patient who does not have a prior history of addiction.”
- “Here are the facts. It is very uncommon for a person with chronic pain to become ‘addicted’ to narcotics IF (1) he doesn’t have a prior history of any addiction and (2) he only takes the medication to treat pain.”
- “Studies have shown that many chronic pain patients can experience significant pain relief with tolerable side effects from opioid narcotic medication when taken daily and no addiction.”

438. In a 2013 *Mallinckrodt Pharmaceuticals Policy Statement Regarding the Treatment of Pain and Control of Opioid Abuse*, which is still available online, Mallinckrodt stated that, “[s]adly, even today, pain frequently remains undiagnosed and either untreated or undertreated” and cites to a report that concludes that “the majority of people with pain use their

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

prescription drugs properly, are not a source of misuse, and should not be stigmatized or denied access because of the misdeeds or carelessness of others.”

439. Marketing Defendants’ suggestions that the opioid epidemic is the result of bad patients who manipulate doctors to obtain opioids illicitly helped further their marketing scheme, but is at odds with the facts. While there are certainly patients who unlawfully obtain opioids, they are a small minority. For example, patients who “doctor-shop”—i.e., visit multiple prescribers to obtain opioid prescriptions—are responsible for roughly 2% of opioid prescriptions. The epidemic of opioid addiction and abuse is overwhelmingly a problem of false marketing (and unconstrained distribution) of the drugs, not problem patients.

440. Marketing Defendants’ efforts to trivialize the risk of addiction were, and remain, unsupported by scientific evidence. Studies have shown that at least 8-12%, and as many as 30-40% of long-term users of opioids experience problems with addiction. According to one study, nearly 60% of patients who used opioids for 90 days continued to use opioids five years later.¹¹⁰ Addiction can result from the use of any opioid, “even at recommended dose”¹¹¹ and the risk increases with chronic (more than three months) use. The CDC has emphasized that “continuing opioid therapy for 3 months substantially increases risk for opioid use disorder.”¹¹²

Falsehood #2: Signs of addiction are “pseudoaddiction,” requiring more opioids

441. Marketing Defendants covered up the occurrence of addiction by attributing it to a made-up condition they called “pseudoaddiction.” Signs of addiction, including shopping for doctors willing to newly write or refill prescriptions for opioids or seeking early refills, actually

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

reflected undertreated pain that should be addressed with more opioids—the medical equivalent of fighting fire by adding fuel.

442. Purdue, through its unbranded imprint *Partners Against Pain*,¹¹³ promoted the concept of pseudoaddiction through at least 2013 on its website. It disseminated the Definitions Related to the Use of Opioids for the Treatment of Pain section of an American Pain Society (“APS”) consensus statement through the website, where APS, who received funding from Defendants, defined pseudoaddiction in the same terms endorsed by Purdue:

Physical dependence, tolerance, and addiction are discrete and different phenomena that are often confused . . . Pseudoaddiction is a term which has been used to describe patient behaviors that may occur when pain is undertreated. Patients with unrelieved pain may become focused on obtaining medications, may ‘clock watch,’ and may otherwise seem inappropriately ‘drug seeking.’ Even such behaviors as illicit drug use and deception can occur in the patient’s efforts to obtain relief. Pseudoaddiction can be distinguished from true addiction in that the behaviors resolve when pain is effectively treated. . . . A patient who is physically dependent on opioids may sometimes continue to use these [medications] despite resolution of pain only to avoid withdrawal. Such use does not necessarily reflect addiction.

443. The Federation of State Medical Boards (“FSMB”), a trade organization representing state medical boards, finances opioid- and pain-specific programs through grants from Defendants. A 2004 version of the FSMB *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain* (“FSMB Guidelines”), and the 2007 book adapted from them, *Responsible Opioid Prescribing*, advanced the concept of pseudoaddiction.

¹¹³ *Partners Against Pain* consists of both a website, styled as an “advocacy community” for better pain care, and medical education resources distributed to prescribers by the sales force. It has existed since at least the early 2000s and has been a vehicle for Purdue to downplay the risks of addiction from long-term opioid use. One early pamphlet, for example, answered concerns about OxyContin’s addictiveness by claiming: “Drug addiction means using a drug to get ‘high’ rather than to relieve pain. You are taking opioid pain medication for medical purposes. The medical purposes are clear and the effects are beneficial, not harmful.”

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

444. *Responsible Opioid Prescribing* was sponsored by Purdue, Endo, and Teva. The FSMB website described the book as the “leading continuing medical education (CME) activity for prescribers of opioid medications.” In all, more than 163,000 copies of *Responsible Opioid Prescribing* were distributed nationally.

445. Janssen sponsored, funded, and edited the *Let’s Talk Pain* website, which in 2009 stated: “pseudoaddiction . . . refers to patient behaviors that may occur when *pain is under-treated* Pseudoaddiction is different from true addiction because such behaviors can be resolved with effective pain management.” This website was accessible online until May 2012.

446. Endo sponsored a National Initiative on Pain Control (NIPC) CME program in 2009 titled *Chronic Opioid Therapy: Understanding Risk While Maximizing Analgesia*, which promoted pseudoaddiction by teaching that a patient’s aberrant behavior was the result of untreated pain. Endo substantially controlled NIPC, an initiative run by the APF, by funding NIPC projects; developing, specifying, and reviewing its content; and distributing NIPC materials. APF internal documents show that APF viewed the NIPC as an “opportunity to generate new revenue” given Endo’s funding commitment.

447. Marketing Defendants also promoted the concept of pseudoaddiction through Dr. Russell Portenoy, a leading KOL for the Defendants. In doing so, he popularized the concept and falsely claimed that pseudoaddiction is substantiated by scientific evidence.

448. The FAQs section of *pain-topics.org*, a now-defunct website to which Mallinckrodt provided funding, also contained misleading information about pseudoaddiction. Specifically, the website advised providers to “keep in mind” that signs of potential drug diversion, rather than signaling “actual” addiction, “may represent pseudoaddiction,” which the website described as

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

behavior that occurs in patients when pain is “undertreated” and includes patients becoming “very focused on obtaining opioid medications and may be erroneously perceived as ‘drug seeking.’”

449. The CDC Guideline for prescribing opioids for chronic pain, a “systematic review of the best available evidence” by a panel excluding experts with conflicts of interest, rejects the concept of pseudoaddiction. The Guideline nowhere recommends that opioid doses be increased if a patient is not experiencing pain relief. To the contrary, the Guideline explains that “[p]atients who do not experience clinically meaningful pain relief early in treatment . . . are unlikely to experience pain relief with longer-term use,”¹¹⁴ and that physicians should “reassess[] pain and function within 1 month” in order to decide whether to “minimize risks of long-term opioid use by discontinuing opioids” because the patient is “not receiving a clear benefit.”¹¹⁵

Falsehood #3: To the extent there is a risk of addiction, it can be easily identified and managed

450. Marketing Defendants falsely instructed prescribers and patients that screening tools, patient contracts, urine drug screens, and similar strategies allow health care providers to safely prescribe opioids to patients, including patients predisposed to addiction, and failed to disclose the lack of evidence that these strategies actually work to mitigate addiction risk. By using screening tools, these Defendants advised doctors that they could identify patients likely to become addicted and safely prescribe to everyone else.

451. Such misrepresentations regarding safe opioid prescribing made health care providers more comfortable prescribing opioids to their patients and patients more comfortable starting chronic opioid therapy. These misrepresentations were especially insidious because Defendants aimed them at general practitioners and family doctors who lack the time and expertise

¹¹⁴ CDC Guideline at 13.

¹¹⁵ *Id.* at 25.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

to closely manage higher-risk patients on opioids. Moreover, these misrepresentations allowed doctors to believe opioid addiction was the result of other prescribers failing to rigorously manage and weed out problem patients, not a risk inherent to the drugs.

452. These Defendants conveyed these safe prescribing messages in nationally distributed marketing materials. A catalogue distributed by Purdue to prescribers across the country and, on information and belief, in the City, included information on screening tools. On information and belief, none of the Defendants disclosed the lack of evidence for efficacy of these tools.

453. Marketing Defendants also promoted screening tools as a reliable means to manage addiction risk in CME programs and scientific conferences, which would have been attended by or were available online, to Huntington prescribers.

454. For example, Purdue sponsored a 2011 CME program titled Managing Patient's Opioid Use: Balancing the Need and Risk. This presentation deceptively instructed prescribers that screening tools, patient agreements, and urine tests prevented “overuse of prescriptions” and “overdose deaths.” Purdue also funded a 2012 CME program called Chronic Pain Management and Opioid Use: Easing Fears, Managing Risks, and Improving Outcomes. The presentation deceptively instructed doctors that, through the use of screening tools, more frequent refills, and other techniques, even high-risk patients showing signs of addiction could be treated with opioids.

455. Purdue used its involvement in the College on the Problems of Drug Dependence (“CPDD”), which promotes scientific research and professional development to support addiction prevention professionals, to promote the idea that addiction risk can be managed. A Purdue employee served on the CPDD board of directors. Purdue presented a disproportionate number of talks—with very different messages from non-Purdue talks—at CPDD conferences. One of

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

Purdue's consistent themes is that "bad apple" patients, not opioids, are the source of the opioid crisis, and that once those patients are identified doctors can safely prescribe opioids without a risk of addiction. Hundreds of addiction treatment specialists from across the country and, upon information and belief, from the City, attended these conferences.

456. Endo paid for a 2007 supplement in the *Journal of Family Practice* written by a doctor who became a member of Endo's speakers' bureau (doctors paid to give talks, typically reserved for the largest prescribers) in 2010. The supplement, entitled *Pain Management Dilemmas in Primary Care: Use of Opioids*, emphasized the effectiveness of screening tools, claiming that patients at high risk of addiction could safely receive chronic opioid therapy using a "maximally structured approach" involving toxicology screens and pill counts.

457. The CDC Guideline confirmed the falsity of Marketing Defendants' claims about the utility of patient screening and management strategies in managing addiction risk. The Guideline notes that there are no studies assessing the effectiveness of risk mitigation strategies—such as screening tools or patient contracts—"for improving outcomes related to overdose, addiction, abuse, or misuse." The CDC Guideline recognized that available risk screening tools "show insufficient accuracy for classification of patients as at low or high risk for [opioid] abuse or misuse" and counseled that doctors "should not overestimate the ability of these tools to rule out risks from long-term opioid therapy."¹¹⁶

Falsehood #4: Opioid withdrawal can be avoided by tapering

458. Purdue's profits, and, upon information and belief, the profits of the other Marketing Defendants, depend on keeping patients on opioids on an ongoing basis. According to internal documents, 87% of Purdue's OxyContin business is driven by continuing prescriptions.

¹¹⁶ CDC Guideline at 28 (emphasis added).

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

Thus, recurring prescriptions to chronic pain patients is a key component of Purdue's business model.

459. To convince prescribers and patients that opioids should be used to treat chronic pain, Defendants had to persuade them of a significant upside to long-term opioid use. Assessing existing evidence, the CDC Guideline found that there is “insufficient evidence to determine the long-term benefits of opioid therapy for chronic pain.”¹¹⁷ In fact, the CDC found that “[n]o evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later (with most placebo-controlled randomized trials ≤ 6 weeks in duration)”¹¹⁸ and that other treatments were more or equally beneficial and less harmful than long-term opioid use. The FDA, too, has recognized the lack of evidence to support long-term opioid use. In 2013, the FDA stated that it was “not aware of adequate and well-controlled studies of opioids use longer than 12 weeks.”¹¹⁹ As a result, the CDC recommends that opioids not be used in the first instance and for treatment of chronic pain; rather, opioids should be used only after prescribers have exhausted alternative treatments.

460. Nevertheless, upon information and belief, Marketing Defendants touted the purported benefits of long-term opioid use, while falsely and misleadingly suggesting that these benefits were supported by scientific evidence.

461. In addition, two prominent professional medical membership organizations, the American Pain Society (“APS”) and the American Academy of Pain Medicine (“AAPM”), each received substantial funding from Marketing Defendants. According to a letter from U.S. Senate Committee on Finance Ranking Member Ron Wyden to Secretary Thomas Price of the U.S.

¹¹⁷ *Id.* at 10.

¹¹⁸ *Id.* at 9.

¹¹⁹ Woodcock Letter, *supra*.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

Department of Health & Human Services, as recently as May 2017, the Corporate Council of AAPM included Endo, Janssen, Purdue and Teva, along with several other pharmaceutical drug companies.¹²⁰ Upon information and belief, Marketing Defendants exercised considerable influence over their work on opioids. Both organizations issued a consensus statement in 1997, *The Use of Opioids for the Treatment of Chronic Pain*, which endorsed opioids to treat chronic pain and claimed that the risk that patients would become addicted to opioids was low. The co-author of the statement, Dr. David Haddox, was at the time a paid speaker for Purdue and later became a senior executive for the company. KOL Dr. Portenoy was the sole consultant. The consensus statement remained on AAPM's website until 2011 and was only removed from AAPM's website after a doctor complained.

462. A past president of the AAPM, Dr. Scott Fishman, who also served as a KOL for Marketing Defendants, stated that he would place the organization “at the forefront” of teaching that “the risks of addiction are . . . small and can be managed.”¹²¹

463. AAPM and APS issued treatment guidelines in 2009 (“AAPM/APS Guidelines”) which continued to recommend the use of opioids to treat chronic pain. Treatment guidelines, like the AAPM/APS Guidelines, were particularly important to Marketing Defendants in securing acceptance for chronic opioid therapy. They are relied upon by doctors, especially general practitioners and family doctors who have no specific training in treating chronic pain. Six of the twenty-one panel members who drafted the AAPM/APS Guidelines received support from Purdue, eight from Teva, nine from Janssen, and ten from Endo.

¹²⁰ Letter from Ron Wyden, Ranking Member, U.S. Senate Committee on Finance, to Honorable Thomas E. Price, Secretary, U.S. Health & Human Services (May 5, 2017), [https://www.finance.senate.gov/imo/media/doc/050817%20corrected%20Senator%20Wyden%20to%20Secretary%20Price%20re%20FDA%20Opioid%20Prescriber%20Working%20Group%20\(5%20May%202017\).pdf](https://www.finance.senate.gov/imo/media/doc/050817%20corrected%20Senator%20Wyden%20to%20Secretary%20Price%20re%20FDA%20Opioid%20Prescriber%20Working%20Group%20(5%20May%202017).pdf).

¹²¹ Interview by Paula Moyer with Scott M. Fishman, M.D., Professor of Anesthesiology and Pain Medicine, Chief of the Division of Pain Medicine, Univ. of Cal., Davis (2005), available at <http://www.medscape.org/viewarticle/500829>.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

464. The AAPM/APS Guidelines promote opioids as “safe and effective” for treating chronic pain. The panel made “strong recommendations” despite “low quality of evidence” and concluded that the risk of addiction is manageable for patients, even with a prior history of drug abuse. One panel member, Dr. Joel Saper, Clinical Professor of Neurology at Michigan State University and founder of the Michigan Headache & Neurological Institute, resigned from the panel because of his concerns that the Guidelines were influenced by contributions that drug companies, including Purdue, Endo, Janssen, and Teva, made to the sponsoring organizations and committee members.

465. Dr. Gilbert Fanciullo, now retired as a professor at Dartmouth College’s Geisel School of Medicine, who served on the AAPM/APS Guidelines panel, has since described them as “skewed” by drug companies and “biased in many important respects,” including the high presumptive maximum dose, lack of suggested mandatory urine toxicology testing, and claims of a low risk of addiction.

466. The AAPM/APS Guidelines are still available online, were reprinted in the *Journal of Pain*, and have influenced not only treating physicians, but also the body of scientific evidence on opioids. According to Google Scholar, they have now been cited at least 1,647 times in academic literature. These Guidelines were available to Huntington prescribers.

467. Purdue specifically marketed its opioids for chronic pain conditions such as low back pain and osteoarthritis, using “vignettes,” or patient exemplars, illustrating the use of opioids to treat patients with these conditions, and inviting doctors to identify patients with these conditions as appropriate candidates for its opioids. Purdue also acknowledged its strategy to encourage prescribers to switch patients from nonsteroidal anti-inflammatory drugs (“NSAIDs,”

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

over-the-counter, non-narcotic pain relievers such as ibuprofen) through articles in “reputable journals” such as AAPM’s and “hearing from respected physicians.”

468. Purdue also published misleading studies to enhance the perception that opioids are effective long-term for chronic pain conditions. One study asserts that OxyContin is safe and effective for the chronic pain condition osteoarthritis. The study, sponsored by Purdue, involved providing oxycodone for 30 days, and then randomizing participants and providing a placebo, an immediate release oxycodone with acetaminophen (like Percocet), or OxyContin. Only 107 of the 167 patients went on to the second phase of the study, and most who withdrew left because of adverse events (nausea, vomiting, drowsiness, dizziness, or headache) or ineffective treatment. Despite relating to a chronic condition, opioids were provided only short-term. The authors even acknowledge that the “results . . . should be confirmed in trials of longer duration to confirm the role of opioids in a chronic condition such as OA [osteoarthritis].”¹²² Yet, the authors conclude that “[t]his clinical experience shows that opioids were well tolerated with only rare incidence of addiction and that tolerance to the analgesic effects was not a clinically significant problem when managing patients with opioids long-term.”¹²³ This statement is not supported by the data—a substantial proportion of patients dropped out because of adverse effects, there was no reported data regarding addiction, and the study was not long-term.

469. Teva deceptively marketed its opioids Actiq and Fentora for chronic pain even though the FDA has expressly limited their use to the treatment of cancer pain in opioid-tolerant individuals.

¹²² Jacques R. Caldwell, et al., *Treatment of Osteoarthritis Pain with Controlled Release Oxycodone or Fixed Combination Oxycodone Plus Acetaminophen Added to Nonsteroidal Antiinflammatory Drugs: A Double Blind, Randomized, Multicenter, Placebo Controlled Trial*, 266.4 Journal of Rheumatology 862-869 (1999).

¹²³ *Id.*

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

470. Both Actiq and Fentora are extremely powerful fentanyl-based opioids. Neither is approved for or has been shown to be safe or effective for chronic pain. Indeed, the FDA expressly prohibited Teva from marketing Actiq for anything but cancer pain, and refused to approve Fentora for the treatment of chronic pain because of the potential harm, including the high risks of “serious and life-threatening adverse events” and abuse—which are greatest in non-cancer patients. The FDA also issued a Public Health Advisory in 2007 emphasizing that Fentora should only be used for cancer patients who are opioid-tolerant and should not be used for any other conditions, such as migraines, post-operative pain, or pain due to injury.

471. Despite this, Teva has conducted a well-funded and deceptive campaign to promote Actiq and Fentora for chronic pain and other non-cancer conditions for which it was not approved, appropriate, or safe. This campaign included the use of CMEs, speaker programs, KOLs, and journal supplements to give doctors the false impression that Actiq and Fentora are safe and effective for treating non-cancer pain, without disclosing the lack of evidence or the FDA’s rejection of their use for chronic pain.

472. For example, Teva paid to have a CME it sponsored, *Opioid-Based Management of Persistent and Breakthrough Pain*, published in a supplement of Pain Medicine News in 2009. The CME instructed doctors that “clinically, broad classification of pain syndromes as either cancer- or noncancer-related has limited utility” and recommended Actiq and Fentora for patients with chronic pain. The CME is still available online.

473. Teva’s sales representatives set up hundreds of speaker programs for doctors, including many non-oncologists, which promoted Actiq and Fentora for the treatment of non-cancer pain.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

474. In December 2011, Teva widely disseminated a journal supplement entitled “*Special Report: An Integrated Risk Evaluation and Mitigation Strategy for Fentanyl Buccal Tablet (FENTORA) and Oral Transmucosal Fentanyl Citrate (ACTIQ)*” to Anesthesiology News, Clinical Oncology News, and Pain Medicine News—three publications that are sent to thousands of anesthesiologists and other medical professionals nationally, including, upon information and belief, in the City. The Special Report openly promotes Fentora for “multiple causes of pain,” and not just cancer pain.

475. Teva’s deceptive marketing gave doctors and patients the false impression that Actiq and Fentora were not only safe and effective for treating chronic pain, but also were approved by the FDA for such uses.

476. On December 28, 2011, the FDA mandated a Risk Evaluation and Mitigation Strategy (REMS) for the class of products for which Teva’s Actiq and Fentora belong, Transmucosal Immediate Release Fentanyl (TIRF). The TIRF REMS programs include mandatory patient and prescriber enrollment forms, as well as certification requirements for prescribers. The forms are not comprehensive and do not, for instance, disclose that addiction can develop when the medications are used as prescribed, nor do they disclose that risks are greatest at higher doses—and patients must already be taking high doses of opioids to be prescribed Actiq and Fentora.

Falsehood #5: Long-term opioid use improves functioning

477. Marketing Defendants also claimed—without evidence—that long-term opioid use would help patients resume their lives and jobs.

478. Marketing Defendants’ materials that, upon information and belief, were distributed or made available in the City, reinforced this message. The 2011 publication *A Policymaker’s Guide* falsely claimed that “multiple clinical studies have shown that opioids are

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

effective in improving” “[d]aily function” and “[o]verall health-related quality of life for people with chronic pain.” A series of medical journal advertisements for OxyContin in 2012 presented “Pain Vignettes”—case studies featuring patients with pain conditions persisting over several months—that implied functional improvement. For example, one advertisement described a “writer with osteoarthritis of the hands” and implied that OxyContin would help him work more effectively. Similarly, starting in at least May of 2011, Endo distributed and made available on its website, opana.com, a pamphlet promoting Opana ER with photographs depicting patients with physically demanding jobs like construction worker and chef, misleadingly implying that the drug would provide long-term pain-relief and functional improvement.

479. Additional illustrative examples are described below:

- a. Janssen sponsored and edited a patient education guide entitled Finding Relief: Pain Management for Older Adults (2009), which states as “a fact” that “opioids may make it easier for people to live normally.” The guide lists expected functional improvements from opioid use, including sleeping through the night, returning to work, recreation, sex, walking, and climbing stairs and states that “[u]sed properly, opioid medications can make it possible for people with chronic pain to ‘return to normal.’”
- b. Responsible Opioid Prescribing (2007), sponsored and distributed by Teva, Endo and Purdue, taught that relief of pain by opioids, by itself, improved patients’ function. The book remains for sale online.
- c. Purdue and Teva sponsored APF’s Treatment Options: A Guide for People Living with Pain (2007), which counseled patients that opioids “give [pain patients] a quality of life we deserve.” The guide was available online until APF shut its doors in May 2012.
- d. Endo’s NIPC website painknowledge.com claimed in 2009 that with opioids, “your level of function should improve; you may find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse.” Elsewhere, the website touted improved quality of life (as well as “improved function”) as benefits of opioid therapy. The grant request that Endo approved for this project specifically indicated NIPC’s intent to make claims of functional improvement, and Endo closely tracked visits to the site.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

- e. Endo was the sole sponsor, through NIPC, of a series of CMEs titled Persistent Pain in the Older Patient, which claimed that chronic opioid therapy has been “shown to reduce pain and improve depressive symptoms and cognitive functioning.” The CME was disseminated via webcast.

480. Mallinckrodt followed suit, stating on its website, in a section on “responsible use” of opioids, claims that “[t]he effective pain management offered by our medicines helps enable patients to stay in the workplace, enjoy interactions with family and friends, and remain an active member of society.”¹²⁴

481. Likewise, Marketing Defendants’ claims that long-term use of opioids improves patient function and quality of life are unsupported by clinical evidence. As noted above, there are no controlled studies of the use of opioids beyond 16 weeks, and there is no evidence that opioids improve patients’ pain and function long-term. On the contrary, the available evidence indicates opioids are not effective to treat chronic pain, and may worsen patients’ health and pain. Increasing the duration of opioid use is strongly associated with an increasing prevalence of mental health conditions (depression, anxiety, post-traumatic stress disorder, and substance abuse), increased psychological distress, and greater health care utilization.

482. As one pain specialist observed, “opioids may work acceptably well for a while, but over the long term, function generally declines, as does general health, mental health, and social functioning. Over time, even high doses of potent opioids often fail to control pain, and these patients are unable to function normally.”¹²⁵ Studies of patients with lower back pain and migraine headaches, for example, have consistently shown that patients experienced deteriorating

¹²⁴ Mallinckrodt Pharmaceuticals, Responsible Use, <http://www.mallinckrodt.com/corporate-responsibility/responsible-use>

¹²⁵ Andrea Rubinstein, *Are We Making Pain Patients Worse?*, Sonoma Med. (Fall 2009), available at <http://www.nbcms.org/about-us/sonoma-county-medical-association/magazine/sonoma-medicine-are-we-making-pain-patients-worse?>.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

function over time, as measured by ability to return to work, physical activity, pain relief, rates of depression, and subjective quality-of-life measures. Analyses of workers' compensation claims have found that workers who take opioids are almost four times more likely to reach costs over \$100,000, stemming from greater side effects and slower returns to work. According to these studies, receiving an opioid for more than seven days also increased patients' risk of being on work disability one year later.

483. The FDA and other federal agencies have, for years, made clear the lack of evidence for claims that the use of opioids for chronic pain improves patients' function and quality of life.¹²⁶ The CDC Guideline, following a "systematic review of the best available evidence," concluded that "[w]hile benefits for pain relief, function and quality of life with long-term opioid use for chronic pain are uncertain, risks associated with long-term opioid use are clearer and significant."¹²⁷ According to the CDC, "for the vast majority of patients, the known, serious, and too-often-fatal risks far outweigh the unproven and transient benefits [of opioids for chronic pain]."¹²⁸

Falsehood #6: Alternative forms of pain relief pose greater risks than opioids

484. In materials Defendants produced, sponsored, or controlled, these Defendants omitted known risks of chronic opioid therapy and emphasized or exaggerated risks of competing

¹²⁶ The FDA has warned other drug makers that claims of improved function and quality of life were misleading. See Warning Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., & Commc'ns, to Doug Boothe, CEO, Actavis Elizabeth LLC (Feb. 18, 2010), (rejecting claims that opioid manufacturer Actavis' opioid, Kadian, had an "overall positive impact on a patient's work, physical and mental functioning, daily activities, or enjoyment of life."); Warning Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., & Commc'ns, to Brian A. Markison, Chairman, President and Chief Executive Officer, King Pharmaceuticals, Inc. (March 24, 2008), (finding the claim that "patients who are treated with [Avinza (morphine sulfate ER)] experience an improvement in their overall function, social function, and ability to perform daily activities . . . has not been demonstrated by substantial evidence or substantial clinical experience."). The FDA's warning letters were available to Defendants on the FDA website.

¹²⁷ CDC Guideline at 2, 18.

¹²⁸ Thomas R. Frieden and Debra Houry, *Reducing the Risks of Relief—The CDC Opioid-Prescribing Guideline*, NEJM, Apr. 21, 2016 at 1503.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

products so that prescribers and patients would be more likely to choose opioids and would favor opioids over other therapies such as over-the-counter acetaminophen or NSAIDs. None of these claims were corroborated by scientific evidence. In fact, several studies have shown that ibuprofen and acetaminophen taken together are better than opioids at relieving pain such as dental pain, low back pain, and moderate acute traumatic pain.¹²⁹

485. In addition to failing to disclose in promotional materials the risks of addiction, abuse, overdose, and death, Marketing Defendants routinely ignored other risks, such as hyperalgesia, a “known serious risk associated with chronic opioid analgesic therapy,”¹³⁰ in which the patient becomes more sensitive to pain over time; hormonal dysfunction; decline in immune function; mental clouding, confusion, and dizziness; increased falls and fractures in the elderly; neonatal abstinence syndrome (when an infant exposed to opioids prenatally withdraws from the drugs after birth); and potentially fatal interactions with alcohol or benzodiazepines, which are used to treat post-traumatic stress disorder and anxiety (conditions that often accompany chronic pain symptoms).

486. Purdue and Teva sponsored APF’s *Treatment Options: A Guide for People Living with Pain* (2007), which counseled patients that opioids differ from NSAIDs in that they have “no ceiling dose” and are therefore the most appropriate treatment for severe pain. The publication inaccurately attributes 10,000 to 20,000 deaths annually to NSAIDs (the actual figure is approximately 3,200—far fewer than from opioids).¹³¹ This publication also warned that risks of NSAIDs increase if “taken for more than a period of months,” with no corresponding warning about opioids.

¹²⁹ Donald Teater, M.D., *Evidence for the Efficacy of Pain Medication*, National Safety Council, October 2014.

¹³⁰ See Martin, *supra*.

¹³¹ The higher figure reflects deaths from all causes.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

487. APF's *Exit Wounds*, sponsored by Purdue and Endo and aimed at veterans, omits warnings of the potentially fatal risk of interactions between opioids and benzodiazepines, a class of drug commonly prescribed to veterans with post-traumatic stress disorder. This book is available from Amazon.com and other retailers.

488. Purdue and Endo sponsored a CME program, *Overview of Management Options*, published by the American Medical Association in 2003, 2007, 2010, and 2013, and discussed further below. The CME was edited by Dr. Russell Portenoy, among others, and taught that NSAIDs and other drugs, but not opioids, are unsafe at high doses.

489. Marketing Defendants frequently contrasted the lack of a ceiling dosage for opioids with the risks of NSAIDs. These Defendants deceptively describe the risks from NSAIDs while failing to disclose the risks from opioids. (*See e.g., Case Challenges in Pain Management: Opioid Therapy for Chronic Pain* (Endo) [describing massive gastrointestinal bleeds from long-term use of NSAIDs and recommending opioids]; *Finding Relief: Pain Management for Older Adults* (Janssen) [NSAIDs caused kidney or liver damage and increased risk of heart attack and stroke, versus opioids, which cause temporary “upset stomach or sleepiness” and constipation].)

490. These omissions are significant and material to patients and prescribers. A Cochrane Collaboration review of evidence relating to the use of opioids for chronic pain found that 22.9% of patients in opioid trials dropped out before the study began because of the “adverse effects” of opioids.¹³²

491. Again, Marketing Defendants' misrepresentations were effective. A study of 7.8 million doctor visits nationwide between 2000 and 2010 found that opioid prescriptions increased

¹³² Meredith Noble M., *Long-Term Opioid Management for Chronic Noncancer Pain (Review)*, Cochrane Database of Systematic Reviews, Issue 1, 11 (2010).

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

from 11.3% to 19.6% of visits while NSAID and acetaminophen prescriptions fell from 38% to 29%. The CDC reports that the quantity of opioids dispensed per capita tripled from 1999 to 2015.

Falsehood #7: Opioid doses can be increased without limit or greater risks

492. Marketing Defendants falsely claimed to prescribers and consumers that opioids could be taken in ever-increasing strengths to obtain pain relief, without disclosing that higher doses increased the risk of addiction and overdose. This was particularly important because patients on opioids for more than a brief period develop tolerance, requiring increasingly high doses to achieve pain relief. These Defendants needed to generate a comfort level among doctors to ensure the doctors maintained patients on the drugs even at the high doses that became necessary. Further, as described in more detail below, Purdue encouraged doctors to prescribe higher doses, rather than prescribe OxyContin more frequently than twice-a-day—despite knowing that OxyContin frequently did not provide 12 hours of relief.

493. Purdue-sponsored publications and CMEs available online also misleadingly suggested that higher opioid doses carried no added risk.

494. Through at least June 2015, Purdue’s *In the Face of Pain* website promoted the notion that if a patient’s doctor did not prescribe a sufficient dose of opioids, the patient should see different doctors until finding a doctor who would.

495. *A Policymaker’s Guide*, the 2011 publication on which, upon information and belief, Purdue collaborated with APF, taught that dose escalations are “sometimes necessary,” but it did not disclose the risks from high dose opioids. Until recently, this publication was still available online.¹³³

¹³³ See <http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf> (last visited Aug. 17, 2018).

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

496. The Purdue-sponsored CME, *Overview of Management Options*, discussed above, again instructed physicians that NSAIDs (like ibuprofen) are unsafe at high doses (because of risks to patients' kidneys), but it did not disclose risks from opioids at high doses.

497. Endo sponsored a website, painknowledge.com, which claimed in 2009 that opioid dosages may be increased until "you are on the right dose of medication for your pain."

498. Endo distributed a pamphlet edited by Dr. Russell Portenoy entitled *Understanding Your Pain: Taking Oral Opioid Analgesics*, which appeared on Endo's website. In Q&A format, it asked "If I take the opioid now, will it work later when I really need it?" The response is, "The dose can be increased. . . You won't 'run out' of pain relief."

499. Janssen sponsored a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which was distributed by its sales force. This guide listed dosage limitations as "disadvantages" of other pain medicines but omitted any discussion of risks of increased opioid dosages.

500. These claims conflict with the scientific evidence. Patients receiving high doses of opioids (e.g., doses greater than 100 mg morphine equivalent dose ("MED") per day) as part of long-term opioid therapy are three to nine times more likely to suffer overdose from opioid-related causes than those on low doses. As compared to available alternative pain remedies, scholars have suggested that tolerance to the respiratory depressive effects of opioids develops at a slower rate than tolerance to opioids' analgesic effects. Accordingly, the practice of continuously escalating doses to match pain tolerance can, in fact, lead to overdose even where opioids are taken as recommended.

501. The CDC Guideline concludes that the "[b]enefits of high-dose opioids for chronic pain are not established" while "there is an increased risk for serious harms related to long-term

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

opioid therapy that appears to be dose-dependent.”¹³⁴ That is why the CDC advises doctors to “avoid increasing doses” above 90 mg MED.¹³⁵

Falsehood #8: OxyContin provides twelve hours of pain relief

502. To convince prescribers and patients to use OxyContin, Purdue misleadingly promoted the drug as providing 12 continuous hours of pain relief with each dose. In reality, OxyContin does not last for 12 hours in many patients, a fact Purdue has known since the product’s launch.

503. OxyContin has been FDA-approved for twice-daily—“Q12”—dosing frequency since its debut in 1996. Purdue sought that dosing frequency in order to maintain a competitive advantage over more frequently dosed opioids. Even so, Purdue has gone well beyond the label’s instructions to take OxyContin every 12 hours. Purdue has affirmatively claimed in its general marketing, including, upon information and belief, to prescribers in the City, that OxyContin lasts for 12 hours and that this is a key advantage of OxyContin, implying that most or all patients would in fact experience continuous pain relief for the full 12 hour dose period. Purdue has also failed to disclose that OxyContin fails to provide 12 hours of pain relief to many patients. These misrepresentations, which Purdue continues to make, are particularly dangerous because inadequate dosing helps fuel addiction, as explained below.

504. From the outset, Purdue leveraged 12-hour dosing to promote OxyContin as providing continuous, round-the-clock pain relief with the convenience of not having to wake to take a third or fourth pill. The 1996 press release for OxyContin touted 12-hour dosing as

¹³⁴ CDC Guideline at 19. The 2016 CDC Guideline reinforces earlier findings announced by the FDA. In 2013, the FDA acknowledged “that the available data do suggest a relationship between increasing opioid dose and risk of certain adverse events.” For example, the FDA noted that studies “appear to credibly suggest a positive association between high-dose opioid use and the risk of overdose and/or overdose mortality.”

¹³⁵ CDC Guideline at 16.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

providing “smooth and sustained pain control all day and all night.” But the FDA has never approved such a marketing claim. To the contrary, the FDA found in 2008, in response to a Citizen Petition by the Connecticut Attorney General, that a “substantial number” of chronic pain patients taking OxyContin experienced “end of dose failure”—*i.e.*, little or no pain relief at the end of the dosing period.

505. Moreover, Purdue itself long has known, dating to its development of OxyContin, that the drug wears off well short of 12 hours in many patients. In one early Purdue clinical trial, a third of patients dropped out because the treatment was ineffective. Researchers changed the rules to allow patients to take supplemental painkillers—“rescue doses”—in between OxyContin doses. In another study, most patients used rescue medication, and 95% resorted to it at least once. In other research conducted by Purdue, the drug wore off in under 6 hours in 25% of patients and in under 10 hours in more than 50%.

506. End-of-dose failure renders OxyContin even more dangerous because patients begin to experience withdrawal symptoms, followed by a euphoric rush with their next dose—a cycle that fuels a craving for OxyContin. For this reason, Dr. Theodore Cicero, a neuropharmacologist at the Washington University School of Medicine in St. Louis, has called OxyContin’s 12-hour dosing “the perfect recipe for addiction.”¹³⁶ Many patients will exacerbate this cycle by taking their next dose ahead of schedule or resorting to a rescue dose of another opioid, increasing the overall amount of opioids they are taking.

507. Purdue has remained committed to 12-hour dosing because it is key to OxyContin’s market dominance and comparatively high price; without this advantage, the drug had little to offer over less expensive, short-acting opioids. In a 2004 letter to the FDA, Purdue acknowledged that

¹³⁶ Harriet Ryan, ‘*You Want a Description of Hell?*’ *OxyContin’s 12-Hour Problem*, L.A. Times, May 5, 2016, available at <http://www.latimes.com/projects/oxycontin-part1/>.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

it had not pursued approval to allow more frequent dosing in the label (*e.g.*, every 8 hours) because 12-hour dosing was “a significant competitive advantage.”

508. While Purdue’s commitment to marketing opioids as a 12-hour drug made it more addictive, Purdue falsely promoted OxyContin as providing “steady state” relief and less likely than other opioids to create a cycle of crash and cravings that fueled addiction and abuse.

509. Promotion of 12-hour dosing, without disclosing its limitations, is misleading because it implies that the pain relief supplied by each dose lasts 12 hours. FDA approval of OxyContin for 12-hour dosing does not give Purdue license to misrepresent the duration of pain relief it provides to patients; moreover, Purdue had a responsibility to correct its label to reflect appropriate dosing and to disclose to prescribers what it knew about OxyContin’s actual duration, but disregarded that responsibility in its pursuit of a marketing advantage.¹³⁷

510. Purdue was also aware of some physicians’ practice of prescribing OxyContin more frequently than 12 hours—a common occurrence. Purdue’s promoted solution to this problem was to increase the dose, rather than the frequency, of prescriptions, even though higher dosing carries its own risks. According to a CDC clinical evidence review, higher opioid doses are related to increased risks of motor vehicle injury, opioid use disorder, and overdoses, and the increased risk increases in a dose-dependent manner.¹³⁸ With higher doses, patients experience higher highs and lower lows, increasing their craving for their next pill. Nationwide, based on an analysis by the *Los Angeles Times*, more than 52% of patients taking OxyContin longer than three months are on

¹³⁷ For example, Kadian, an opioid manufactured by Allergan, was designed to be taken once a day, but the label acknowledges and advises dosing of up to every 12 hours for certain patients.

¹³⁸ Mark J. Edlund, *The Role of Opioid Prescription in Incident Opioid Abuse and Dependence Among Individuals with Chronic Non-cancer Pain*, 30 Clin. J. Pain 557–564 (2014); Woodcock Letter, *supra*.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

doses greater than 60 milligrams per day—which converts to the 90 MED that the CDC Guideline urges prescribers to “avoid” or “carefully justify.”¹³⁹

Falsehood #9: New formulations of certain opioids successfully deter abuse

511. Rather than take the widespread abuse and addiction to opioids as reason to cease their untruthful marketing claims and efforts, Defendants Purdue and Endo seized them as a market opportunity. These companies oversold their abuse-deterrent formulations (“ADF”) as a solution to opioid abuse and as a reason that doctors could continue to safely prescribe their opioids. Purdue’s and Endo’s false and misleading marketing of the benefits of its ADF opioids preserved and expanded their sales and influenced prescribers to discount evidence of opioid addiction and abuse and attribute it to other, less safe opioids—thereby prolonging the opioid epidemic in the City.

Purdue’s Deceptive Marketing of Reformulated OxyContin and Hysingla ER.

512. Reformulated ADF OxyContin was approved by the FDA in April 2010. It was not until 2013 that the FDA, in response to a Citizen Petition filed by Purdue, permitted reference to the abuse-deterrent properties in its label. However, the FDA made clear that abuse-deterrent properties do not stop tampering but only make it harder to modify the pills. ADF pills can still be snorted and injected if tampered with, and these pills are still sought after by abusers because of their high likability when snorted. Further, ADF properties do not reduce oral abuse—the most common form of abuse—in any way. When Hysingla ER (extended-release hydrocodone) launched in 2014, the product included similar abuse-deterrent properties and limitations.

¹³⁹ CDC Guideline at 16.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

513. It is unlikely a coincidence that reformulated OxyContin was introduced shortly before generic versions of OxyContin were to become available, threatening to erode Purdue's market share and the price it could charge. Through a Citizen Petition, Purdue was able to secure a determination by the FDA in April 2013 that original OxyContin should be removed from the market as unsafe (lacking abuse-deterrent properties), and thus non-ADF generic copies could not be sold. As a result, Purdue extended its branded exclusivity for OxyContin until the patent protection on the abuse-deterrent coating expires.

514. Purdue nonetheless touted its introduction of ADF opioids as evidence of its good corporate citizenship and commitment to address the opioid crisis. Touting the benefits of ADF opioids, Purdue's website asserts, for instance: "we are acutely aware of the public health risks these powerful medications create . . . That's why we work with health experts, law enforcement, and government agencies on efforts to reduce the risks of opioid abuse and misuse . . ."¹⁴⁰

515. Purdue knew or should have known that "reformulated OxyContin is not better at tamper resistance than the original OxyContin"¹⁴¹ and is still regularly tampered with and abused.

516. Websites and message boards used by drug abusers and others, such as bluelight.org and reddit.com, report a variety of ways to tamper with OxyContin and Hysingla ER, including through grinding, microwaving then freezing, or drinking soda or fruit juice in which a tablet is dissolved. A publicly available Citizen Petition submitted to the FDA in 2016 by a drug manufacturing firm challenged Purdue's abuse-deterrent labeling based on the firm's ability to easily prepare so-called abuse deterrent OxyContin to be snorted or injected.

¹⁴⁰ Purdue website, *Opioids With Abuse-Deterrent Properties*, available at <http://www.purduepharma.com/healthcare-professionals/responsible-use-of-opioids/opioids-with-abuse-deterrentproperties/>.

¹⁴¹ Hr'g Test. of Dr. Mohan Rao at 1615:7-10, In re OxyContin, No. 1:04-md-01603-SHS (SDNY Oct. 7, 2013), ECF No. 613.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

517. *One-third* of the patients in a 2015 study defeated the ADF mechanism and were able to continue inhaling or injecting the drug. To the extent that the abuse of Purdue's ADF opioids was reduced, there was no meaningful reduction in drug abuse, as many addicts simply shifted to other drugs such as heroin.

518. A 2013 article presented by Purdue employees based on review of data from poison control centers, concluded that ADF OxyContin can reduce abuse, but it ignored important negative findings. The study revealed that abuse merely shifted to other drugs and that, when the actual incidence of harmful exposures was calculated, there were *more* harmful exposures to opioids (including heroin) after the reformulation of OxyContin. In short, the article deceptively emphasized the advantages and ignored the disadvantages of ADF OxyContin.

519. The CDC Guideline confirms that “[n]o studies” support the notion that “abuse-deterrent technologies [are] a risk mitigation strategy for deterring or preventing abuse,” noting that the technologies “do not prevent opioid abuse through oral intake, the most common route of opioid abuse, and can still be abused by non-oral routes.”¹⁴² Tom Frieden, the Director of the CDC, reported that his staff could not find “any evidence showing the updated opioids [ADF opioids] actually reduce rates of addiction, overdoses, or death.”¹⁴³

520. In 2015, claiming a need to further assess its data, Purdue abruptly withdrew a supplemental new drug application related to reformulated OxyContin one day before FDA staff was to release its assessment of the application. The staff review preceded an FDA advisory committee meeting related to new studies by Purdue “evaluating the misuse and/or abuse of reformulated OxyContin” and whether those studies “have demonstrated that the reformulated

¹⁴² CDC Guideline at 22 (emphasis added).

¹⁴³ Matthew Perrone, *Drugmakers Push Profitable, but Unproven, Opioid Solution*, AP (Jan. 2, 2017), <https://www.publicintegrity.org/2016/12/15/20544/drugmakers-push-profitable-unproven-opioid-solution>.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

OxyContin product has had a meaningful impact on abuse.”¹⁴⁴ Upon information and belief, Purdue never presented the data to the FDA because the data would not have supported claims that OxyContin’s ADF properties reduced abuse or misuse.

521. Despite the qualifying language in Purdue’s label and its own evidence—and lack of evidence—regarding the impact of its ADF opioids in reducing abuse, Dr. J. David Haddox, the Vice President of Health Policy for Purdue, falsely claimed in 2016 that the evidence does not show that Purdue’s ADF opioids are being abused in large numbers.

Endo’s Deceptive Marketing of Reformulated Opana ER.

522. In a strategy that closely resembled Purdue’s, Endo, as the expiration of its patent exclusivity for Opana ER neared, and aware that it needed to be able to compete with other opioids, like OxyContin, that were being introduced as ADFs, also made abuse-deterrence a key to its marketing strategy.

523. In December 2011, Endo obtained approval for a new formulation of Opana ER that added a hard coating that the company claimed made it crush-resistant. Even prior to its approval, the FDA advised Endo in January 2011 that it could not market new Opana ER as abuse-deterrent. The FDA found that such promotional claims “may provide a false sense of security since the product may be chewed and ground for subsequent abuse.”¹⁴⁵ In other words, Opana ER was still crushable. Indeed, in its approval package, Endo admitted that “[i]t has not been established that this new formulation of Opana ER is less subject to misuse, abuse, diversion, overdose, or addiction.”

¹⁴⁴ Meeting Notice, Joint Meeting of the Drug Safety and Risk Management Advisory Committee and the Anesthetic and Analgesic Drug Products Advisory Committee; Notice of Meeting, May 25, 2015, 80 FR 30686.

¹⁴⁵ Attorney General of the State of New York, In the Matter of Endo Health Solutions Inc. and Endo Pharmaceuticals Inc., Assurance No.: 15-2228, Assurance of Discontinuance Under Executive Law Section 63, Subdivision 15 at 5.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

524. Nonetheless, in August of 2012, Endo submitted a confidential Citizen Petition asking the FDA for permission to change its label to indicate that Opana ER was abuse-resistant, both in that it was less able to be crushed and snorted, and that it was resistant to “aqueous extraction,” or injection by syringe. Borrowing a page from Purdue’s playbook, Endo announced it would withdraw original Opana ER from the market and sought a determination that its decision was made for safety reasons (its lack of abuse deterrence). That would prevent generic copies of original Opana ER from competitors, such as Impax Laboratories (“Impax”), which had sought approval to sell a generic version of the drug.

525. Endo then sued the FDA, seeking to force expedited consideration of its Citizen Petition. The court filings confirmed Endo’s true motives: in a declaration submitted with its lawsuit, Endo’s chief operating officer indicated that a generic version of Opana ER would decrease the company’s revenue by up to \$135 million per year. Endo also claimed that if the FDA did not block generic competition, \$125 million, which Endo spent on developing the reformulated drug to “promote the public welfare,” would be lost.¹⁴⁶ The FDA responded that: “Endo’s true interest in expedited FDA consideration stems from business concerns rather than protection of the public health.”¹⁴⁷

526. Despite Endo’s purported concern with public safety, not only did Endo continue to distribute original Opana ER for nine months after the reformulated version became available, it declined to recall original Opana ER despite its dangers. In fact, Endo also claimed in September

¹⁴⁶ Plaintiff’s Opposition to Defendants’ and Intervenor’s Motions to Dismiss and Plaintiff’s Reply in Support of Motion for Preliminary Injunction (“Endo Br.”), *Endo Pharmaceuticals Inc. v. U.S. Food and Drug Administration, et al.*, No. 1:12-cv-01936, Doc. 23 at 20 (D.D.C. Dec.14, 2012).

¹⁴⁷ Defendants’ Response to the Court’s November 30, 2012 Order, *Endo Pharmaceuticals Inc. v. U.S. Food and Drug Administration, et al.*, No. 1:12-cv-01936, Doc. 9 at 6 (D.D.C. Dec. 3, 2012).

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

2012 to be “proud” that “almost all remaining inventory” of the original Opana ER had “been utilized.”¹⁴⁸

527. In its Citizen Petition, Endo asserted that redesigned Opana ER had “safety advantages.” However, in rejecting the Petition in a 2013 decision, the FDA found that “study data show that the reformulated version’s extended-release features can be compromised when subjected to … cutting, grinding, or chewing.” The FDA also determined that “reformulated Opana ER” could also be “readily prepared for injection and more easily be prepared for injection[.]” In fact, the FDA warned that preliminary data—including in Endo’s own studies—suggested that a higher percentage of reformulated Opana ER abuse is via injection than was the case with the original formulation.

528. Over time, evidence continued to mount that injection was becoming the preferred means of abusing Opana ER, making Opana ER *less safe* than the original formulation. Injection carries risks of HIV, Hepatitis C, and, in reformulated Opana ER’s specific case, the blood-clotting disorder thrombotic thrombocytopenic purpura (TTP), which can cause kidney failure. In 2009, only 3% of Opana ER abuse was by intravenous means. Since the reformulation, injection of Opana ER increased by more than 500%.

529. Nevertheless, Endo continued to market the drug as tamper-resistant and abuse-deterrent and did not disclose evidence that Opana was easier to abuse intravenously.

530. In its written materials, Endo marketed Opana ER as having been *designed* to be crush resistant, knowing that this would (falsely) imply that Opana ER actually *was* crush resistant and that this crush-resistant quality would make Opana ER less likely to be abused. For example,

¹⁴⁸ *Id.*; Endo News Release, Sept. 6, 2012 (Ex. L to Rurka Decl.) *Endo Pharmaceuticals Inc. v. U.S. Food and Drug Administration, et al.*, No. 1:12-cv-01936 ,Doc. 18-4(D.D.C. Dec. 9, 2012).

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

a June 14, 2012 Endo press release announced “the completion of the company’s transition of its OPANA ER franchise to the new formulation designed to be crush resistant.”¹⁴⁹ The press release further stated that: “We firmly believe that the new formulation of OPANA ER, coupled with our long-term commitment to awareness and education around appropriate use of opioids will benefit patients, physicians and payers.”¹⁵⁰ In September 2012, another Endo press release stressed that reformulated Opana ER employed “INTAC Technology” and continued to describe the drug as “designed to be crush-resistant.”¹⁵¹

531. Similarly, journal advertisements that appeared in April 2013 stated Opana ER was “designed to be crush resistant.”

532. In a 2016 settlement with Endo, the New York Attorney General found that statements that Opana ER was “designed to be, or is crush resistant” were false and misleading because there was no difference in the ability to extract the narcotic from Opana ER. The New York Attorney General also found that Endo failed to disclose its own knowledge of the crushability of redesigned Opana ER in its marketing to insurers and pharmacy benefit managers, which also would have impacted the availability of Opana ER in the City.

Other Marketing Defendants’ Misrepresentations Regarding Abuse Deterrence.

533. A guide for prescribers under Actavis’s copyright deceptively represents that Kadian is more difficult to abuse and less addictive than other opioids. The guide declares that “unique pharmaceutical formulation of KADIAN may offer some protection from extraction of morphine sulfate for intravenous use by illicit users,” and “KADIAN may be less likely to be

¹⁴⁹ Ex. E to Rurka Decl., *Endo Pharmaceuticals Inc. v. U.S. Food and Drug Administration, et al.*, No. 12-v-1936, Doc. 18-2 at 1 (D.D.C. Dec. 9, 2012).

¹⁵⁰ *Id.*

¹⁵¹ Endo News Release, Sept. 6, 2012 (Ex. L to Rurka Decl.) *Endo Pharmaceuticals Inc. v. U.S. Food and Drug Administration, et al.*, No. 1:12-cv-01936, Doc. 18-4 (D.D.C. Dec. 9, 2012).

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

abused by health care providers and illicit users” because of its “[s]low onset of action.” Kadian, however, was not approved by the FDA as abuse deterrent, and, upon information and belief, Actavis had no studies to suggest it was.

534. Mallinckrodt promoted both Exalgo (extended-release hydromorphone) and Xartemis XR (oxycodone and acetaminophen) as specifically formulated to reduce abuse. For example, Mallinckrodt’s promotional materials stated that “the physical properties of EXALGO may make it difficult to extract the active ingredient using common forms of physical and chemical tampering, including chewing, crushing and dissolving.”¹⁵² One member of the FDA’s Controlled Substance Staff, however, noted in 2010 that hydromorphone has “a high abuse potential comparable to oxycodone” and further stated that “we predict that Exalgo will have high levels of abuse and diversion.”¹⁵³

535. With respect to Xartemis XR, Mallinckrodt’s promotional materials stated that “XARTEMIS XR has technology that requires abusers to exert additional effort to extract the active ingredient from the large quantity of inactive and deterrent ingredients.”¹⁵⁴ In anticipation of Xartemis XR’s approval, Mallinckrodt added 150-200 sales representatives to promote it, and CEO Mark Trudeau said the drug could generate “hundreds of millions in revenue.”¹⁵⁵

536. While Marketing Defendants promote patented technology as the solution to opioid abuse and addiction, none of their “technology” addresses the most common form of abuse—oral

¹⁵² Press Release, Covidien, FDA Approves Mallinckrodt’s EXALGO® (hydromorphone HCl) Extended-Release Tablets 32 mg (CII) for Opioid-Tolerant Patients with Moderate-to-Severe Chronic Pain (Aug. 27, 2012), <http://newsroom.medtronic.com/phoenix.zhtml?c=251324&p=irol-newsArticle&ID=2004159>

¹⁵³ 2010 Meeting Materials, Anesthetic and Analgesic Drug Products Advisory Committee, at 157-58, FDA, <https://wayback.archive-it.org/7993/20170403223634/https://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/AnestheticAndAnalgesicDrugProductsAdvisoryCommittee/ucm193298.htm>.

¹⁵⁴ Mallinckrodt, Responsible Use of Opioid Pain Medications (Mar. 7, 2014).

¹⁵⁵ Samantha Liss, Mallinckrodt Banks on New Painkillers for Sales, St. Louis Bus. J. (Dec. 30, 2013), <http://argentcapital.com/mallinckrodt-banks-on-new-painkillers-for-sales/>.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

ingestion—and their statements regarding abuse-deterrent formulations give the misleading impression that these reformulated opioids can be prescribed safely.

537. In sum, each of the nine categories of misrepresentations discussed above regarding the use of opioids to treat chronic pain was not supported by, or was contrary to, the scientific evidence. In addition, the misrepresentations and omissions set forth above and elsewhere in this Complaint are misleading and contrary to the Marketing Defendants' products' labels.

2. The Marketing Defendants Disseminated Their Misleading Messages about Opioids Through Multiple Channels

538. The Marketing Defendants' false marketing campaign not only targeted the medical community who had to treat chronic pain, but also patients who experience chronic pain.

539. The Marketing Defendants utilized various channels to carry out their marketing scheme of targeting the medical community and patients with deceptive information about opioids: (1) "Front Groups" with the appearance of independence from the Marketing Defendants; (2) so-called "key opinion leaders" ("KOLs"), that is, doctors who were paid by the Marketing Defendants to promote their pro-opioid message; (3) CME programs controlled and/or funded by the Marketing Defendants; (4) branded advertising; (5) unbranded advertising; (6) publications; (7) direct, targeted communications with prescribers by sales representatives or "detailers"; and (8) speakers bureaus and programs.

i. The Marketing Defendants Directed Front Groups to Deceptively Promote Opioid Use

540. Patient advocacy groups and professional associations also became vehicles to reach prescribers, patients, and policymakers. Marketing Defendants exerted influence and effective control over the messaging by these groups by providing major funding directly to them, as well as through KOLs who served on their boards. These "Front Groups" put out patient education materials, treatment guidelines and CMEs that supported the use of opioids for chronic

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

pain, overstated their benefits, and understated their risks.¹⁵⁶ Defendants funded these Front Groups in order to ensure supportive messages from these seemingly neutral and credible third parties, and their funding did, in fact, ensure such supportive messages—often at the expense of their own constituencies.

541. “Patient advocacy organizations and professional societies like the Front Groups ‘play a significant role in shaping health policy debates, setting national guidelines for patient treatment, raising disease awareness, and educating the public.’”¹⁵⁷ “Even small organizations—with ‘their large numbers and credibility with policymakers and the public’—have ‘extensive influence in specific disease areas.’ Larger organizations with extensive funding and outreach capabilities ‘likely have a substantial effect on policies relevant to their industry sponsors.’”¹⁵⁸ Indeed, the U.S. Senate’s report, *Fueling an Epidemic: Exposing the Financial Ties Between Opioid Manufacturers and Third Party Advocacy Groups*,¹⁵⁹ which arose out of a 2017 Senate investigation and, drawing on disclosures from Purdue, Janssen, and other opioid manufacturers, “provides the first comprehensive snapshot of the financial connections between opioid manufacturers and advocacy groups and professional societies operating in the area of opioids policy,”¹⁶⁰ found that the Marketing Defendants made millions of dollars of contributions to various Front Groups.

¹⁵⁶ U.S. Senate Homeland Security & Governmental Affairs Committee, Ranking Members’ Office, February 12, 2018 <https://www.hsdl.org/?abstract&did=808171> (“*Fueling an Epidemic*”), at p. 3.

¹⁵⁷ *Id.* at p. 2.

¹⁵⁸ *Id.*

¹⁵⁹ U.S. Senate Homeland Security & Governmental Affairs Committee, Ranking Members’ Office, February 12, 2018 <https://www.hsdl.org/?abstract&did=808171> (“*Fueling an Epidemic*”), at 1.

¹⁶⁰ *Id.*

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

542. The Marketing Defendants also “made substantial payments to individual group executives, staff members, board members, and advisory board members” affiliated with the Front Groups subject to the Senate Committee’s study.¹⁶¹

543. As the Senate *Fueling an Epidemic* Report found, the Front Groups “amplified or issued messages that reinforce industry efforts to promote opioid prescription and use, including guidelines and policies minimizing the risk of addiction and promoting opioids for chronic pain.”¹⁶² They also “lobbied to change laws directed at curbing opioid use, strongly criticized landmark CDC guidelines on opioid prescribing, and challenged legal efforts to hold physicians and industry executives responsible for overprescribing and misbranding.”¹⁶³

544. The Marketing Defendants took an active role in guiding, reviewing, and approving many of the false and misleading statements issued by the Front Groups, ensuring that Defendants were consistently in control of their content. By funding, directing, editing, approving, and distributing these materials, Defendants exercised control over and adopted their false and deceptive messages and acted in concert with the Front Groups and through the Front groups, with each other to deceptively promote the use of opioids for the treatment of chronic pain.

American Pain Foundation

545. The most prominent of the Front Groups was the American Pain Foundation (“APF”). While APF held itself out as an independent patient advocacy organization, in reality it received 90% of its funding in 2010 from the drug and medical-device industry, including from defendants Purdue, Endo, Janssen and Cephalon. APF received more than \$10 million in funding from opioid manufacturers from 2007 until it closed its doors in May 2012. By 2011, APF was

¹⁶¹ *Id.* at p. 10.

¹⁶² *Id.* at 12-15.

¹⁶³ *Id.* at 12.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

entirely dependent on incoming grants from Defendants Purdue, Cephalon, Endo, and others to avoid using its line of credit. Endo was APF's largest donor and provided more than half of its \$10 million in funding from 2007 to 2012.

546. For example, APF published a guide sponsored by Cephalon and Purdue titled *Treatment Options: A Guide for People Living with Pain*, and distributed 17,200 copies of this guide in one year alone, according to its 2007 annual report. This guide contains multiple misrepresentations regarding opioid use which are discussed below.

547. APF also developed the National Initiative on Pain Control (“NIPC”), which ran a facially unaffiliated website, www.painknowledge.com. NIPC promoted itself as an education initiative led by its expert leadership team, including purported experts in the pain management field. NIPC published unaccredited prescriber education programs (accredited programs are reviewed by a third party and must meet certain requirements of independence from pharmaceutical companies), including a series of “dinner dialogues.” But it was Endo that substantially controlled NIPC, by funding NIPC projects, developing, specifying, and reviewing its content, and distributing NIPC materials. Endo’s control of NIPC was such that Endo listed it as one of its “professional education initiative[s]” in a plan Endo submitted to the FDA. Yet, Endo’s involvement in NIPC was nowhere disclosed on the website pages describing NIPC or www.painknowledge.org. Endo estimated it would reach 60,000 prescribers through NIPC.

548. APF was often called upon to provide “patient representatives” for the Marketing Defendants’ promotional activities, including for Purdue’s “Partners Against Pain” and Janssen’s “Let’s Talk Pain.” Although APF presented itself as a patient advocacy organization, it functioned largely as an advocate for the interests of the Marketing Defendants, not patients. As Purdue told

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

APF in 2001, the basis of a grant to the organization was Purdue’s desire to strategically align its investments in nonprofit organizations that share [its] business interests.

549. In practice, APF operated in close collaboration with Defendants, submitting grant proposals seeking to fund activities and publications suggested by Defendants and assisting in marketing projects for Defendants.

550. This alignment of interests was expressed most forcefully in the fact that Purdue hired APF to provide consulting services on its marketing initiatives. Purdue and APF entered into a “Master Consulting Services” Agreement on September 14, 2011. That agreement gave Purdue substantial rights to control APF’s work related to a specific promotional project. Moreover, based on the assignment of particular Purdue “contacts” for each project and APF’s periodic reporting on their progress, the agreement enabled Purdue to be regularly aware of the misrepresentations APF was disseminating regarding the use of opioids to treat chronic pain in connection with that project. The agreement gave Purdue—but not APF—the right to end the project (and, thus, APF’s funding) for any reason. Even for projects not produced during the terms of this Agreement, the Agreement demonstrates APF’s lack of independence and willingness to harness itself to Purdue’s control and commercial interests, which would have carried across all of APF’s work.

551. APF’s Board of Directors was largely comprised of doctors who were on the Marketing Defendants’ payrolls, either as consultants or speakers at medical events. The close relationship between APF and the Marketing Defendants demonstrates APF’s clear lack of independence, in its finances, management, and mission, and its willingness to allow Marketing Defendants to control its activities and messages supports an inference that each Defendant that worked with it was able to exercise editorial control over its publications—even when Defendants’

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

messages contradicted APF’s internal conclusions. For example, a roundtable convened by APF and funded by Endo also acknowledged the lack of evidence to support chronic opioid therapy. APF’s formal summary of the meeting notes concluded that: “[An] important barrier[] to appropriate opioid management [is] the lack of confirmatory data about the long-term safety and efficacy of opioids in non-cancer chronic pain, amid cumulative clinical evidence.”

552. In May 2012, the U.S. Senate Finance Committee began looking into APF to determine the links, financial and otherwise, between the organization and the manufacturers of opioid painkillers. Within days of being targeted by the Senate investigation, APF’s board voted to dissolve the organization “due to irreparable economic circumstances.” APF then “cease[d] to exist, effective immediately.” Without support from Marketing Defendants, to whom APF could no longer be helpful, APF was no longer financially viable.

American Academy of Pain Medicine and the American Pain Society

553. The American Academy of Pain Medicine (“AAPM”) and the American Pain Society (“APS”) are professional medical societies, each of which received substantial funding from Defendants from 2009 to 2013. In 1997, AAPM issued a “consensus” statement that endorsed opioids to treat chronic pain and claimed that the risk that patients would become addicted to opioids was low.¹⁶⁴ The Chair of the committee that issued the statement, Dr. J. David Haddox, was at the time a paid speaker for Purdue. The sole consultant to the committee was Dr. Russell Portenoy, who was also a spokesperson for Purdue. The consensus statement, which also formed the foundation of the 1998 Guidelines, was published on the AAPM’s website.

¹⁶⁴ *The Use of Opioids for the Treatment of Chronic Pain*, APS & AAPM (1997). Available at <http://www.stgeorgeutah.com/wp-content/uploads/2016/05/OPIOIDES.DOLORCRONICO.pdf> (as viewed August 18, 2017).

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

554. AAPM's corporate council includes Purdue, Depomed, Teva and other pharmaceutical companies. AAPM's past presidents include Haddox (1998), Dr. Scott Fishman ("Fishman") (2005), Dr. Perry G. Fine ("Fine") (2011) and Dr. Lynn R. Webster ("Webster") (2013), all of whose connections to the opioid manufacturers are well-documented as set forth below.

555. Fishman, who also served as a KOL for Marketing Defendants, stated that he would place the organization "at the forefront" of teaching that "the risks of addiction are . . . small and can be managed."¹⁶⁵

556. AAPM received over \$2.2 million in funding since 2009 from opioid manufacturers. AAPM maintained a corporate relations council, whose members paid \$25,000 per year (on top of other funding) to participate. The benefits included allowing members to present educational programs at off-site dinner symposia in connection with AAPM's marquee event—its annual meeting held in Palm Springs, California, or other resort locations.

557. AAPM describes the annual event as an "exclusive venue" for offering CMEs to doctors. Membership in the corporate relations council also allows drug company executives and marketing staff to meet with AAPM executive committee members in small settings. Defendants Endo, Purdue, and Cephalon were members of the council and presented deceptive programs to doctors who attended this annual event. The conferences sponsored by AAPM heavily emphasized CME sessions on opioids—37 out of roughly 40 at one conference alone.

558. AAPM's staff understood that they and their industry funders were engaged in a common task. Defendants were able to influence AAPM through both their significant and regular funding and the leadership of pro-opioid KOLs within the organization.

¹⁶⁵ Interview by Paula Moyer with Scott M. Fishman, M.D., Professor of Anesthesiology and Pain Medicine, Chief of the Division of Pain Medicine, Univ. of Cal., Davis (2005), available at <http://www.medscape.org/viewarticle/500829>.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

559. AAPM and APS issued their own guidelines in 2009 (“2009 Guidelines”). AAPM, with the assistance, prompting, involvement, and funding of Defendants, issued the treatment guidelines discussed herein, and continued to recommend the use of opioids to treat chronic pain. Fourteen of the 21 panel members who drafted the 2009 Guidelines, including KOL Dr. Fine, received support from Defendants Janssen, Cephalon, Endo, and Purdue. Of these individuals, six received support from Purdue, eight from Teva, nine from Janssen, and nine from Endo.

560. One panel member, Dr. Joel Saper, Clinical Professor of Neurology at Michigan State University and founder of the Michigan Headache & Neurological Institute, resigned from the panel because of his concerns that the Guidelines were influenced by contributions that drug companies, including Purdue, Endo, Janssen, and Teva, made to the sponsoring organizations and committee members.

561. Dr. Gilbert Fanciullo, now retired as a professor at Dartmouth College’s Geisel School of Medicine, who also served on the AAPM/APS Guidelines panel, has since described them as “skewed” by drug companies and “biased in many important respects,” including the high presumptive maximum dose, lack of suggested mandatory urine toxicology testing, and claims of a low risk of addiction.

562. The 2009 Guidelines have been a particularly effective channel of deception. They have influenced not only treating physicians, but also the scientific literature on opioids; they were reprinted in the *Journal of Pain*, have been cited hundreds of times in academic literature, were disseminated during the relevant period, and were and are available online. Treatment guidelines are especially influential with primary care physicians and family doctors to whom Marketing Defendants promoted opioids, whose lack of specialized training in pain management and opioids

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

makes them more reliant on, and less able to evaluate, these guidelines. For that reason, the CDC has recognized that treatment guidelines can “change prescribing practices.”¹⁶⁶

563. The 2009 Guidelines are relied upon by doctors, especially general practitioners and family doctors who have no specific training in treating chronic pain.

564. The Marketing Defendants widely cited and promoted the 2009 Guidelines without disclosing the lack of evidence to support their conclusions, their involvement in the development of the Guidelines or their financial backing of the authors of these Guidelines. For example, a speaker presentation prepared by Endo in 2009 titled *The Role of Opana ER in the Management of Moderate to Severe Chronic Pain* relies on the AAPM/APS Guidelines while omitting their disclaimer regarding the lack of evidence for recommending the use of opioids for chronic pain.

Federation of State Medical Boards

565. The Federation of State Medical Boards (“FSMB”) is a trade organization representing the various state medical boards in the United States. The state boards that comprise the FSMB membership have the power to license doctors, investigate complaints, and discipline physicians.

566. The FSMB finances opioid- and pain-specific programs through grants from Defendants.

567. Since 1998, the FSMB has been developing treatment guidelines for the use of opioids for the treatment of pain. The 1998 version, Model Guidelines for the Use of Controlled Substances for the Treatment of Pain (“1998 Guidelines”) was produced “in collaboration with pharmaceutical companies.” The 1998 Guidelines that the pharmaceutical companies helped author taught not that opioids could be appropriate in only limited cases after other treatments had

¹⁶⁶ 2016 CDC Guideline at 2.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

failed, but that opioids were “essential” for treatment of chronic pain, including as a first prescription option.

568. A 2004 iteration of the 1998 Guidelines and the 2007 book, *Responsible Opioid Prescribing*, also made the same claims as the 1998 Guidelines. These guidelines were posted online and were available to and intended to reach physicians nationwide, including in the City of Huntington.

569. FSMB’s 2007 publication *Responsible Opioid Prescribing* was backed largely by drug manufacturers, including Purdue, Endo and Cephalon. The publication also received support from the American Pain Foundation and the American Academy of Pain Medicine. The publication was written by Dr. Fishman, and Dr. Fine served on the Board of Advisors. In all, 163,131 copies of *Responsible Opioid Prescribing* were distributed by state medical boards (and through the boards, to practicing doctors). The FSMB website describes the book as “the leading continuing medical education (CME) activity for prescribers of opioid medications.” This publication asserted that opioid therapy to relieve pain and improve function is a legitimate medical practice for acute and chronic pain of both cancer and non-cancer origins; that pain is under-treated, and that patients should not be denied opioid medications except in light of clear evidence that such medications are harmful to the patient..

570. The Marketing Defendants relied on the 1998 Guidelines to convey the alarming message that “under-treatment of pain” would result in official discipline, but no discipline would result if opioids were prescribed as part of an ongoing patient relationship and prescription decisions were documented. FSMB turned doctors’ fear of discipline on its head: doctors, who used to believe that they would be disciplined if their patients became addicted to opioids, were

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

taught instead that they would be punished if they failed to prescribe opioids to their patients with chronic pain.

The Alliance for Patient Access

571. Founded in 2006, the Alliance for Patient Access (“APA”) is a self-described patient advocacy and health professional organization that styles itself as “a national network of physicians dedicated to ensuring patient access to approved therapies and appropriate clinical care.”¹⁶⁷ It is run by Woodberry Associates LLC, a lobbying firm that was also established in 2006.¹⁶⁸ As of June 2017, the APA listed 30 “Associate Members and Financial Supporters.” The list includes Johnson & Johnson, Endo, Mallinckrodt, Purdue and Cephalon.

572. APA’s board members have also directly received substantial funding from pharmaceutical companies.¹⁶⁹ For instance, board vice president Dr. Srinivas Nalamachu (“Nalamachu”), who practices in Kansas, received more than \$800,000 from 2013 through 2015 from pharmaceutical companies—nearly all of it from manufacturers of opioids or drugs that treat opioids’ side effects, including from defendants Endo, Purdue and Cephalon. Nalamachu’s clinic was raided by FBI agents in connection with an investigation of Insys and its payment of kickbacks to physicians who prescribed Subsys. Other board members include Dr. Robert A. Yapundich from North Carolina, who received \$215,000 from 2013 through 2015 from pharmaceutical companies, including payments by defendants Cephalon and Mallinckrodt; Dr. Jack D. Schim from California, who received more than \$240,000 between 2013 and 2015 from pharmaceutical

¹⁶⁷ About AfPA, The Alliance for Patient Access, <http://allianceforpatientaccess.org/about-afpa/#membership> (last visited Jan. 4, 2018). References herein to APA include two affiliated groups: the Global Alliance for Patient Access and the Institute for Patient Access.

¹⁶⁸ Mary Chris Jaklevic, *Non-profit Alliance for Patient Access uses journalists and politicians to push Big Pharma’s agenda*, Health News Review (Oct. 2, 2017), <https://www.healthnewsreview.org/2017/10/non-profit-alliance-patient-access-uses-journalists-politicians-push-big-pharmas-agenda/> (hereinafter “Jaklevic, *Non-profit Alliance for Patient Access*”).

¹⁶⁹ All information concerning pharmaceutical company payments to doctors in this paragraph is from ProPublica’s Dollars for Docs database, available at <https://projects.propublica.org/docdollars/>.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

companies, including defendants Endo, Mallinckrodt and Cephalon; Dr. Howard Hoffberg from Maryland, who received \$153,000 between 2013 and 2015 from pharmaceutical companies, including defendants Endo, Purdue, Mallinckrodt and Cephalon; and Dr. Robin K. Dore from California, who received \$700,000 between 2013 and 2015 from pharmaceutical companies.

573. Among its activities, APA issued a “white paper” titled “Prescription Pain Medication: Preserving Patient Access While Curbing Abuse.”¹⁷⁰ Among other things, the white paper criticizes prescription monitoring programs, purporting to express concern that they are burdensome, not user friendly, and of questionable efficacy:

Prescription monitoring programs that are difficult to use and cumbersome can place substantial burdens on physicians and their staff, ultimately leading many to stop prescribing pain medications altogether. This forces patients to seek pain relief medications elsewhere, which may be much less convenient and familiar and may even be dangerous or illegal.

* * *

In some states, physicians who fail to consult prescription monitoring databases before prescribing pain medications for their patients are subject to fines; those who repeatedly fail to consult the databases face loss of their professional licensure. Such penalties seem excessive and may inadvertently target older physicians in rural areas who may not be facile with computers and may not have the requisite office staff. Moreover, threatening and fining physicians in an attempt to induce compliance with prescription monitoring programs represents a system based on punishment as opposed to incentives. . . .

We cannot merely assume that these programs will reduce prescription pain medication use and abuse.¹⁷¹

574. The white paper also purports to express concern about policies that have been enacted in response to the prevalence of pill mills:

Although well intentioned, many of the policies designed to address this problem have made it difficult for legitimate pain management

¹⁷⁰ Prescription Pain Medication: Preserving Patient Access While Curbing Abuse, Institute for Patient Access (Oct. 2013), http://1yh21u3cjptv3xjder1dco9mx5s. wpengine.netdna-cdn.com/wp-content/uploads/2013/12/PT_White-Paper_Finala.pdf.

¹⁷¹ *Id.* at 4-5 (footnote omitted).

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

centers to operate. For instance, in some states, [pain management centers] must be owned by physicians or professional corporations, must have a Board certified medical director, may need to pay for annual inspections, and are subject to increased record keeping and reporting requirements. . . . [I]t is not even certain that the regulations are helping prevent abuses.¹⁷²

575. In addition, in an echo of earlier industry efforts to push back against what they termed “opiophobia,” the white paper laments the stigma associated with prescribing and taking pain medication:

Both pain patients and physicians can face negative perceptions and outright stigma. When patients with chronic pain can’t get their prescriptions for pain medication filled at a pharmacy, they may feel like they are doing something wrong—or even criminal. . . . Physicians can face similar stigma from peers. Physicians in non-pain specialty areas often look down on those who specialize in pain management—a situation fueled by the numerous regulations and fines that surround prescription pain medications.¹⁷³

576. In conclusion, the white paper states that “[p]rescription pain medications, and specifically the opioids, can provide substantial relief for people who are recovering from surgery, afflicted by chronic painful diseases, or experiencing pain associated with other conditions that does not adequately respond to over-the-counter drugs.”¹⁷⁴

577. The APA also issues “Patient Access Champion” financial awards to members of Congress, including 50 such awards in 2015. The awards were funded by a \$7.8 million donation from unnamed donors. While the awards are ostensibly given for protecting patients’ access to Medicare, and are thus touted by their recipients as demonstrating a commitment to protecting the rights of senior citizens and the middle class, they appear to be given to provide cover to and reward members of Congress who have supported the APA’s agenda.

¹⁷² *Id.* at 5-6.

¹⁷³ *Id.* at 6.

¹⁷⁴ *Id.* at 7.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

578. The APA also lobbies Congress directly. In 2015, the APA signed onto a letter supporting legislation proposed to limit the ability of the DEA to police pill mills by enforcing the “suspicious orders” provision of the Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C. §801 *et seq.* (“CSA” or “Controlled Substances Act”).¹⁷⁵ The AAPM is also a signatory to this letter. An internal U.S. Department of Justice (“DOJ”) memo stated that the proposed bill “could actually result in increased diversion, abuse, and public health and safety consequences”¹⁷⁶ and, according to DEA chief administrative law judge John J. Mulrooney (“Mulrooney”), the law would make it “all but logically impossible” to prosecute manufacturers and distributors, like the defendants here, in the federal courts.¹⁷⁷ The law passed both houses of Congress and was signed into law in 2016.

The U.S. Pain Foundation

579. The U.S. Pain Foundation (“USPF”) was another Front Group with systematic connections and interpersonal relationships with the Marketing Defendants. The USPF was one of the largest recipients of contributions from the Marketing Defendants, collecting nearly \$3 million in payments between 2012 and 2015 alone. The USPF was also a critical component of the Marketing Defendants’ lobbying efforts to reduce the limits on over-prescription. The U.S. Pain Foundation advertises its ties to the Marketing Defendants, listing opioid manufacturers like Pfizer, Teva, Depomed, Endo, Purdue, McNeil (*i.e.*, Janssen), and Mallinckrodt as “Platinum,”

¹⁷⁵ Letter from Alliance for Patient Access, et al., to Congressmen Tom Marino, Marsha Blackburn, Peter Welch, and Judy Chu (Jan. 26, 2015), http://www.hoparx.org/images/hopa/advocacy/advocacy-activities/FINAL_Patient_Access_Letter_of_Support_House_Bill.pdf.

¹⁷⁶ Bill Whitaker, Ex-DEA Agent: Opioid Crisis Fueled by Drug Industry and Congress, CBS News (Oct. 17, 2017), <https://www.cbsnews.com/news/ex-dea-agent-opioid-crisis-fueled-by-drug-industry-and-congress/> (hereinafter, “Whitaker, Opioid Crisis Fueled by Drug Industry”).

¹⁷⁷ John J. Mulrooney, II & Katherine E. Legel, Current Navigation Points in Drug Diversion Law: Hidden Rocks in Shallow, Murky, Drug-Infested Waters, 101 Marquette L. Rev. (forthcoming Feb. 2018), <https://www.documentcloud.org/documents/4108121-Marquette-Law-Review-Mulrooney-Legel.html>.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

“Gold,” and “Basic” corporate members.¹⁷⁸ Industry Front Groups like the American Academy of Pain Management, the American Academy of Pain Medicine, the American Pain Society, and PhRMA are also members of varying levels in the USPF.

American Geriatrics Society

580. The American Geriatrics Society (“AGS”) was another Front Group with systematic connections and interpersonal relationships with the Marketing Defendants. AGS was a large recipient of contributions from the Marketing Defendants, including Endo, Purdue and Janssen. AGS contracted with Purdue, Endo and Janssen to disseminate guidelines regarding the use of opioids for chronic pain in 2002 (*The Management of Persistent Pain in Older Persons*, hereinafter “2002 AGS Guidelines”) and 2009 (Pharmacological Management of Persistent Pain in Older Persons,¹⁷⁹ hereinafter “2009 AGS Guidelines”). According to news reports, AGS has received at least \$344,000 in funding from opioid manufacturers since 2009.¹⁸⁰ AGS’s complicity in the common purpose with the Marketing Defendants is evidenced by the fact that AGS internal discussions in August 2009 reveal that it did not want to receive-up front funding from drug companies, which would suggest drug company influence, but would instead accept commercial support to disseminate pro-opioid publications.

581. The 2009 AGS Guidelines recommended that “[a]ll patients with moderate to severe pain . . . should be considered for opioid therapy.” The panel made “strong recommendations” in this regard despite “low quality of evidence” and concluded that the risk of

¹⁷⁸ *Id.* at 12; Transparency, U.S. Pain Foundation, <https://uspainfoundation.org/transparency/> (last accessed on March 9, 2018).

¹⁷⁹ *Pharmacological Management of Persistent Pain in Older Persons*, 57 J. Am. Geriatrics Soc’y 1331, 1339, 1342 (2009), available at <https://www.nhqualitycampaign.org/files/AmericanGeriatricSociety-PainGuidelines2009.pdf> (last accessed on March 9, 2018).

¹⁸⁰ John Fauber & Ellen Gabler, “Narcotic Painkiller Use Booming Among Elderly,” *Milwaukee J. Sentinel*, May 30, 2012.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

addiction is manageable for patients, even with a prior history of drug abuse.¹⁸¹ These Guidelines further recommended that “the risks [of addiction] are exceedingly low in older patients with no current or past history of substance abuse.” These recommendations are not supported by any study or other reliable scientific evidence. Nevertheless, they have been cited over 1,833 times in Google Scholar (which allows users to search scholarly publications that would have been relied on by researchers and prescribers) since their 2009 publication and as recently as this year.

582. Representatives of the Marketing Defendants, often at informal meetings at conferences, suggested activities, lobbying efforts and publications for AGS to pursue. AGS then submitted grant proposals seeking to fund these activities and publications, knowing that drug companies would support projects conceived as a result of these communications.

583. Members of AGS Board of Directors were doctors who were on the Marketing Defendants’ payrolls, either as consultants or speakers at medical events. As described below, many of the KOLs also served in leadership positions within the AGS.

ii. The Marketing Defendants Paid Key Opinion Leaders to Deceptively Promote Opioid Use

584. To falsely promote their opioids, the Marketing Defendants paid and cultivated a select circle of doctors who were chosen and sponsored by the Marketing Defendants for their supportive messages. As set forth below, pro-opioid doctors have been at the hub of the Marketing Defendants’ well-funded, pervasive marketing scheme since its inception and were used to create the grave misperception science and legitimate medical professionals favored the wider and broader use of opioids. These doctors include Dr. Russell Portenoy and Dr. Lynn Webster, as set forth in this section, as well as Dr. Perry Fine and Dr. Scott Fishman, as set forth in further below.

¹⁸¹ AGS 2009 Guidelines at 1342.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

585. Although these KOLs were funded by the Marketing Defendants, the KOLs were used extensively to present the appearance that unbiased and reliable medical research supporting the broad use of opioid therapy for chronic pain had been conducted and was being reported on by independent medical professionals.

586. As the Marketing Defendants' false marketing scheme picked up steam, these pro-opioid KOLs wrote, consulted on, edited, and lent their names to books and articles, and gave speeches and CMEs supportive of opioid therapy for chronic pain. They served on committees that developed treatment guidelines that strongly encouraged the use of opioids to treat chronic pain and they were placed on boards of pro-opioid advocacy groups and professional societies that develop, select, and present CMEs.

587. Through use of their KOLs and strategic placement of these KOLs throughout every critical distribution channel of information within the medical community, the Marketing Defendants were able to exert control of each of these modalities through which doctors receive their information.

588. In return for their pro-opioid advocacy, the Marketing Defendants' KOLs received money, prestige, recognition, research funding, and avenues to publish. For example, Dr. Webster has received funding from Endo, Purdue, and Cephalon. Dr. Fine has received funding from Janssen, Cephalon, Endo, and Purdue.

589. The Marketing Defendants carefully vetted their KOLs to ensure that they were likely to remain on-message and supportive of the Marketing Defendants' agenda. The Marketing Defendants also kept close tabs on the content of the materials published by these KOLs. And, of course, the Marketing Defendants kept these KOLs well-funded to enable them to push the Marketing Defendants' deceptive message out to the medical community.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

590. Once the Marketing Defendants identified and funded KOLs and those KOLs began to publish “scientific” papers supporting the Marketing Defendants’ false position that opioids were safe and effective for treatment of chronic pain, the Marketing Defendants poured significant funds and resources into a marketing machine that widely cited and promoted their KOLs and studies or articles by their KOLs to drive prescription of opioids for chronic pain. The Marketing Defendants cited to, distributed, and marketed these studies and articles by their KOLs as if they were independent medical literature so that it would be well-received by the medical community. By contrast, the Marketing Defendants did not support, acknowledge, or disseminate the truly independent publications of doctors critical of the use of chronic opioid therapy.

591. In their promotion of the use of opioids to treat chronic pain, the Marketing Defendants’ KOLs knew that their statements were false and misleading, or they recklessly disregarded the truth in doing so, but they continued to publish their misstatements to benefit themselves and the Marketing Defendants.

Dr. Russell Portenoy

592. In 1986, Dr. Russell Portenoy, who later became Chairman of the Department of Pain Medicine and Palliative Care at Beth Israel Medical Center in New York while at the same time serving as a top spokesperson for drug companies, published an article reporting that “[f]ew substantial gains in employment or social function could be attributed to the institution of opioid therapy.”¹⁸²

593. Writing in 1994, Dr. Portenoy described the prevailing attitudes regarding the dangers of long-term use of opioids:

The traditional approach to chronic non-malignant pain does not accept the long-term administration of opioid drugs. This

¹⁸² R. Portenoy & K. Foley, *Chronic Use of Opioid Analgesics in Non-Malignant Pain: Report of 38 cases*, 25(2) Pain 171 (1986).

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

perspective has been justified by the perceived likelihood of tolerance, which would attenuate any beneficial effects over time, and the potential for side effects, worsening disability, and addiction. According to conventional thinking, the initial response to an opioid drug may appear favorable, with partial analgesia and salutary mood changes, but adverse effects inevitably occur thereafter. It is assumed that the motivation to improve function will cease as mental clouding occurs and the belief takes hold that the drug can, by itself, return the patient to a normal life. Serious management problems are anticipated, including difficulty in discontinuing a problematic therapy and the development of drug seeking behavior induced by the desire to maintain analgesic effects, avoid withdrawal, and perpetuate reinforcing psychic effects. There is an implicit assumption that little separates these outcomes from the highly aberrant behaviors associated with addiction.¹⁸³

(Emphasis added.) According to Dr. Portenoy, the foregoing problems could constitute “compelling reasons to reject long-term opioid administration as a therapeutic strategy in all but the most desperate cases of chronic nonmalignant pain.”¹⁸⁴

594. Despite having taken this position on long-term opioid treatment, Dr. Portenoy ended up becoming a spokesperson for Purdue and other Marketing Defendants, promoting the use of prescription opioids and minimizing their risks. A respected leader in the field of pain treatment, Dr. Portenoy was highly influential. Dr. Andrew Kolodny, cofounder of Physicians for Responsible Opioid Prescribing, described him “lecturing around the country as a religious-like figure. The megaphone for Portenoy is Purdue, which flies in people to resorts to hear him speak. It was a compelling message: ‘Docs have been letting patients suffer; nobody really gets addicted; it’s been studied.’”¹⁸⁵

¹⁸³ R. Portenoy, *Opioid Therapy for Chronic Nonmalignant Pain: Current Status*, 1 Progress in Pain Res. & Mgmt., 247-287 (H.L. Fields and J.C. Liebeskind eds., 1994) (emphasis added).

¹⁸⁴ *Id.*

¹⁸⁵ Sam Quinones, *Dreamland: The True Tale of America’s Opiate Epidemic* 314 (Bloomsbury Press 2015).

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

595. As one organizer of CME seminars who worked with Portenoy and Purdue pointed out, “had Portenoy not had Purdue’s money behind him, he would have published some papers, made some speeches, and his influence would have been minor. With Purdue’s millions behind him, his message, which dovetailed with their marketing plans, was hugely magnified.”¹⁸⁶

596. Dr. Portenoy was also a critical component of the Marketing Defendants’ control over their Front Groups. Specifically, Dr. Portenoy sat as a Director on the board of the APF. He was also the President of the APS.

597. In recent years, some of the Marketing Defendants’ KOLs have conceded that many of their past claims in support of opioid use lacked evidence or support in the scientific literature.¹⁸⁷ Dr. Portenoy has now admitted that he minimized the risks of opioids, and that he “gave innumerable lectures in the late 1980s and ‘90s about addiction that weren’t true.”¹⁸⁸ He mused, “Did I teach about pain management, specifically about opioid therapy, in a way that reflects misinformation? Well, against the standards of 2012, I guess I did . . .”¹⁸⁹

598. In a 2011 interview released by Physicians for Responsible Opioid Prescribing, Portenoy stated that his earlier work purposefully relied on evidence that was not “real” and left real evidence behind:

I gave so many lectures to primary care audiences in which the Porter and Jick article was just one piece of data that I would then cite, and I would cite six, seven, maybe ten different avenues of thought or avenues of evidence, none of which represented real evidence, and yet what I was trying to do was to create a narrative so that the primary care audience would look at this information in [total] and feel more comfortable about opioids in a way they hadn’t

¹⁸⁶ *Id.* at 136.

¹⁸⁷ See, e.g., John Fauber, *Painkiller boom fueled by networking*, Journal Sentinel (Feb. 18, 2012), <http://archive.jsonline.com/watchdog/watchdogreports/painkiller-boom-fueled-by-networking-dp3p2rn-139609053.html/> (reporting that a key Endo KOL acknowledged that opioid marketing went too far).

¹⁸⁸ Thomas Catan and Evan Perez, *A Pain-Drug Champion Has Second Thoughts*, The Wall Street Journal (Dec. 17, 2012, 11:36am), <https://www.wsj.com/articles/SB10001424127887324478304578173342657044604>.

¹⁸⁹ *Id.*

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

before. In essence this was education to destigmatize [opioids], and because the primary goal was to destigmatize, we often left evidence behind.¹⁹⁰

599. Several years earlier, when interviewed by journalist Barry Meier for his 2003 book, *Pain Killer*, Dr. Portenoy was more direct: “It was pseudoscience. I guess I’m going to have always to live with that one.”¹⁹¹

Dr. Lynn Webster

600. Another KOL, Dr. Lynn Webster, was the co-founder and Chief Medical Director of the Lifetree Clinical Research & Pain Clinic in Salt Lake City, Utah. Dr. Webster was President in 2013 and is a current board member of AAPM, a Front Group that ardently supports chronic opioid therapy. He is a Senior Editor of *Pain Medicine*, the same journal that published Endo’s special advertising supplements touting Opana ER. Dr. Webster was the author of numerous CMEs sponsored by Cephalon, Endo, and Purdue. At the same time, Dr. Webster was receiving significant funding from Defendants (including nearly \$2 million from Cephalon).

601. Dr. Webster created and promoted the Opioid Risk Tool (“ORT”), a five question, one-minute screening tool relying on patient self-reports that purportedly allows doctors to manage the risk that their patients will become addicted to or abuse opioids. The claimed ability to pre-sort patients likely to become addicted is an important tool in giving doctors confidence to prescribe opioids long-term, and for this reason, references to screening appear in various industry-supported guidelines. Versions of Dr. Webster’s ORT appear on, or are linked to, websites run by Endo, Janssen, and Purdue. In 2011, Dr. Webster presented, via webinar, a program sponsored by Purdue titled, *Managing Patient’s Opioid Use: Balancing the Need and the Risk*. Dr. Webster recommended use of risk screening tools, urine testing, and patient agreements to prevent “overuse

¹⁹⁰ Jacobs, *One-paragraph letter*; Andrew Kolodny, *Opioids for Chronic Pain: Addiction is NOT Rare*, YouTube (Oct. 30, 2011), <https://www.youtube.com/watch?v=DgyuBWN9D4w&feature=youtu.be>.

¹⁹¹ Meier, at 277.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

of prescriptions” and “overdose deaths.” This webinar was available to and was intended to reach doctors in Plaintiffs’ County.

602. Dr. Webster was himself tied to numerous overdose deaths. He and the Lifetree Clinic were investigated by the DEA for overprescribing opioids after twenty patients died from overdoses. In keeping with the Marketing Defendants’ promotional messages, Dr. Webster apparently believed the solution to patients’ tolerance or addictive behaviors was more opioids: he prescribed staggering quantities of pills.

603. At an AAPM annual meeting held February 22 through 25, 2006, Cephalon sponsored a presentation by Webster and others titled, “Open-label study of fentanyl effervescent buccal tablets in patients with chronic pain and breakthrough pain: Interim safety results.” The presentation’s agenda description states: “Most patients with chronic pain experience episodes of breakthrough pain, yet no currently available pharmacologic agent is ideal for its treatment.” The presentation purports to cover a study analyzing the safety of a new form of fentanyl buccal tablets in the chronic pain setting and promises to show the “[i]nterim results of this study suggest that FEBT is safe and well-tolerated in patients with chronic pain and BTP.” This CME effectively amounted to off-label promotion of Cephalon’s opioids—the only drugs in this category—for chronic pain, even though they were approved only for cancer pain.

604. Cephalon sponsored a CME written by Dr. Webster, *Optimizing Opioid Treatment for Breakthrough Pain*, offered by Medscape, LLC from September 28, 2007 through December 15, 2008. The CME taught that non-opioid analgesics and combination opioids containing non-opioids such as aspirin and acetaminophen are less effective at treating breakthrough pain because of dose limitations on the non-opioid component.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

Dr. Perry Fine

605. Dr. Perry Fine's ties to the Marketing Defendants are well documented. He has authored articles and testified in court cases and before state and federal committees, and he, too, has argued against legislation restricting high-dose opioid prescription for non-cancer patients. He has served on Purdue's advisory board, provided medical legal consulting for Janssen, and participated in CME activities for Endo, along with serving in these capacities for several other drug companies. He co-chaired the APS/AAPM Opioid Guideline Panel, served as treasurer of the AAPM from 2007 to 2010 and as president of that group from 2011 to 2013, and was on the board of directors of APF.

606. Multiple videos feature Fine delivering educational talks about prescription opioids. He even testified at trial that the 1,500 pills a month prescribed to celebrity Anna Nicole Smith for pain did not make her an addict before her death.

607. He has also acknowledged having failed to disclose numerous conflicts of interest. For example, Dr. Fine failed to fully disclose payments received as required by his employer, the University of Utah—telling the university that he had received under \$5,000 in 2010 from Johnson & Johnson for providing “educational” services, but Johnson & Johnson’s website states that the company paid him \$32,017 for consulting, promotional talks, meals and travel that year.

608. Dr. Fine and Dr. Portenoy co-wrote *A Clinical Guide to Opioid Analgesia*, in which they downplayed the risks of opioid treatment, such as respiratory depression and addiction:

At clinically appropriate doses, . . . respiratory rate typically does not decline. Tolerance to the respiratory effects usually develops quickly, and doses can be steadily increased without risk. Overall, the literature provides evidence that the outcomes of drug abuse and addiction are rare among patients who receive opioids for

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

a short period (ie, for acute pain) and among those with no history of abuse who receive long-term therapy for medical indications.¹⁹²

609. In November 2010, Dr. Fine and others published an article presenting the results of another Cephalon-sponsored study titled “Long-Term Safety and Tolerability of Fentanyl Buccal Tablet for the Treatment of Breakthrough Pain in Opioid-Tolerant Patients with Chronic Pain: An 18-Month Study.”¹⁹³ In that article, Dr. Fine explained that the 18-month “open-label” study “assessed the safety and tolerability of FBT [Fentora] for the [long-term] treatment of BTP in a large cohort . . . of opioid-tolerant patients receiving around-the-clock . . . opioids for noncancer pain.” The article acknowledged that: (a) “[t]here has been a steady increase in the use of opioids for the management of chronic noncancer pain over the past two decades”; (b) the “widespread acceptance” had led to the publishing of practice guidelines “to provide evidence-and consensus-based recommendations for the optimal use of opioids in the management of chronic pain”; and (c) those guidelines lacked “data assessing the long-term benefits and harms of opioid therapy for chronic pain.”¹⁹⁴

610. The article concluded: “[T]he safety and tolerability profile of FBT in this study was generally typical of a potent opioid. The [adverse events] observed were, in most cases, predictable, manageable, and tolerable.” They also conclude that the number of abuse-related events was “small.”¹⁹⁵

611. Multiple videos feature Dr. Fine delivering educational talks about the drugs. In one video from 2011 titled “Optimizing Opioid Therapy,” he sets forth a “Guideline for Chronic

¹⁹² Perry G. Fine, MD and Russell K. Portenoy, MD, *A Clinical Guide to Opioid Analgesia* 20 and 34, McGraw-Hill Companies (2004), <http://www.thblack.com/links/RSD/OpioidHandbook.pdf>.

¹⁹³ Perry G. Fine, et al., *Long-Term Safety and Tolerability of Fentanyl Buccal Tablet for the Treatment of Breakthrough Pain in Opioid-Tolerant Patients with Chronic Pain: An 18-Month Study*, 40(5) J. Pain & Symptom Management 747-60 (Nov. 2010).

¹⁹⁴ *Id.*

¹⁹⁵ *Id.*

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

Opioid Therapy” discussing “opioid rotation” (switching from one opioid to another) not only for cancer patients, but for non-cancer patients, and suggests it may take four or five switches over a person’s “lifetime” to manage pain.¹⁹⁶ He states the “goal is to improve effectiveness which is different from efficacy and safety.” Rather, for chronic pain patients, effectiveness “is a balance of therapeutic good and adverse events *over the course of years.*” The entire program assumes that opioids are appropriate treatment over a “protracted period of time” and even over a patient’s entire “lifetime.” He even suggests that opioids can be used to treat *sleep apnea*. He further states that the associated risks of addiction and abuse can be managed by doctors and evaluated with “tools,” but leaves that for “a whole other lecture.”¹⁹⁷

Dr. Scott Fishman

612. Dr. Scott Fishman is a physician whose ties to the opioid drug industry are legion. He has served as an APF board member and as president of the AAPM, and has participated yearly in numerous CME activities for which he received “market rate honoraria.” As discussed below, he has authored publications, including the seminal guides on opioid prescribing, which were funded by the Marketing Defendants. He has also worked to oppose legislation requiring doctors and others to consult pain specialists before prescribing high doses of opioids to non-cancer patients. He has himself acknowledged his failure to disclose all potential conflicts of interest in a letter in the *Journal of the American Medical Association* titled “Incomplete Financial Disclosures in a Letter on Reducing Opioid Abuse and Diversion.”¹⁹⁸

¹⁹⁶ Perry A. Fine, Safe and Effective Opioid Rotation, YouTube (Nov. 8, 2012), https://www.youtube.com/watch?v=_G3II9yqgXI.

¹⁹⁷ *Id.*

¹⁹⁸ Scott M. Fishman, *Incomplete Financial Disclosures in a Letter on Reducing Opioid Abuse and Diversion*, 306(13) JAMA 1445 (2011); Tracy Weber & Charles Ornstein, *Two Leaders in Pain Treatment Have Long Ties to Drug Industry*, ProPublica (Dec. 23, 2011, 2:14 PM), <https://www.propublica.org/article/two-leaders-in-pain-treatment-have-long-ties-to-drug-industry> (hereinafter “Weber, *Two Leaders in Pain*”).

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

613. In 2007, Dr. Fishman authored a physician's guide on the use of opioids to treat chronic pain titled *Responsible Opioid Prescribing*, which promoted the notion that long-term opioid treatment was a viable and safe option for treating chronic pain.

614. In 2012, Dr. Fishman updated the guide and continued emphasizing the "catastrophic" "under-treatment" of pain and the "crisis" such under-treatment created:

Given the magnitude of the problems related to opioid analgesics, it can be tempting to resort to draconian solutions: clinicians may simply stop prescribing opioids, or legislation intended to improve pharmacovigilance may inadvertently curtail patient access to care. As we work to reduce diversion and misuse of prescription opioids, it's critical to remember that the problem of unrelieved pain remains as urgent as ever.¹⁹⁹

615. The updated guide still assures that "[o]pioid therapy to relieve pain and improve function is legitimate medical practice for acute and chronic pain of both cancer and noncancer origins."²⁰⁰

616. In another guide by Dr. Fishman, he continues to downplay the risk of addiction: "I believe clinicians must be very careful with the label 'addict.' I draw a distinction between a 'chemical coper' and an addict."²⁰¹ The guide also continues to present symptoms of addiction as symptoms of "pseudoaddiction."

¹⁹⁹ Scott M. Fishman, *Responsible Opioid Prescribing: A Guide for Michigan Clinicians*, 10-11 (Waterford Life Sciences 2012).

²⁰⁰ *Id.*

²⁰¹ Scott M. Fishman, *Listening to Pain: A Physician's Guide to Improving Pain Management Through Better Communication* 45 (Oxford University Press 2012).

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

iii. The Marketing Defendants Disseminated Their Misrepresentations Through Continuing Medical Education Programs

617. Now that the Marketing Defendants had both a group of physician promoters and had built a false body of “literature,” Defendants needed to make sure their false marketing message was widely distributed.

618. One way the Marketing Defendants aggressively distributed their false message was through thousands of Continuing Medical Education courses (“CMEs”).

619. A CME is a professional education program provided to doctors. Doctors are required to attend a certain number and, often, type of CME programs each year as a condition of their licensure. These programs are delivered in person, often in connection with professional organizations’ conferences, and online, or through written publications. Doctors rely on CMEs not only to satisfy licensing requirements, but also to get information on new developments in medicine or to deepen their knowledge in specific areas of practice. Because CMEs typically are taught by KOLs who are highly respected in their fields, and are thought to reflect these physicians’ medical expertise, they can be especially influential with doctors.

620. The countless doctors and other health care professionals who participate in accredited CMEs constitute an enormously important audience for opioid reeducation. As one target, Defendants aimed to reach general practitioners, whose broad area of practice and lack of expertise and specialized training in pain management made them particularly dependent upon CMEs and, as a result, especially susceptible to the Marketing Defendants’ deceptions.

621. The Marketing Defendants sponsored CMEs that were delivered thousands of times, promoting chronic opioid therapy and supporting and disseminating the deceptive and biased messages described in this Complaint. These CMEs, while often generically titled to relate

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

to the treatment of chronic pain, focus on opioids to the exclusion of alternative treatments, inflate the benefits of opioids, and frequently omit or downplay their risks and adverse effects.

622. Cephalon sponsored numerous CME programs, which were made widely available through organizations like Medscape, LLC (“Medscape”) and which disseminated false and misleading information to physicians across the country.

623. Another Cephalon-sponsored CME presentation titled *Breakthrough Pain: Treatment Rationale with Opioids* was available on Medscape starting September 16, 2003 and was given by a self-professed pain management doctor who treated “previously operated back, complex pain syndromes, the neuropathies, and interstitial cystitis.” He describes the pain process as a non-time-dependent continuum that requires a balanced analgesia approach using “targeted pharmacotherapeutics to affect multiple points in the pain-signaling pathway.”²⁰² The doctor lists fentanyl as one of the most effective opioids available for treating breakthrough pain, describing its use as an expected and normal part of the pain management process. Nowhere in the CME is cancer or cancer-related pain even mentioned, despite FDA restrictions that fentanyl use be limited to cancer-related pain.

624. Teva paid to have a CME it sponsored, *Opioid-Based Management of Persistent and Breakthrough Pain*, published in a supplement of Pain Medicine News in 2009. The CME instructed doctors that “clinically, broad classification of pain syndromes as either cancer- or noncancer-related has limited utility” and recommended Actiq and Fentora for patients with chronic pain. The CME is still available online.

625. *Responsible Opioid Prescribing* was sponsored by Purdue, Endo and Teva. The FSMB website described it as the “leading continuing medical education (CME) activity for

²⁰² Daniel S. Bennett, *Breakthrough Pain: Treatment Rationale With Opioids*, Medscape, <http://www.medscape.org/viewarticle/461612> (last visited Oct. 10, 2017).

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

prescribers of opioid medications.” Endo sales representatives distributed copies of *Responsible Opioid Prescribing* with a special introductory letter from Dr. Scott Fishman.

626. In all, more than 163,000 copies of *Responsible Opioid Prescribing* were distributed nationally.

627. The American Medical Association (“AMA”) recognized the impropriety that pharmaceutical company-funded CMEs creates, stating that support from drug companies with a financial interest in the content being promoted “creates conditions in which external interests could influence the availability and/or content” of the programs and urges that “[w]hen possible, CME[s] should be provided without such support or the participation of individuals who have financial interests in the education subject matter.”²⁰³

628. Physicians attended or reviewed CMEs sponsored by the Marketing Defendants during the relevant time period and were misled by them.

629. By sponsoring CME programs put on by Front Groups like APF, AAPM, and others, the Marketing Defendants could expect instructors to deliver messages favorable to them, as these organizations were dependent on the Marketing Defendants for other projects. The sponsoring organizations honored this principle by hiring pro-opioid KOLs to give talks that supported chronic opioid therapy. Marketing Defendant-driven content in these CMEs had a direct and immediate effect on prescribers’ views on opioids. Producers of CMEs and the Marketing Defendants both measured the effects of CMEs on prescribers’ views on opioids and their absorption of specific messages, confirming the strategic marketing purpose in supporting them.

²⁰³ Opinion 9.0115, *Financial Relationships with Industry in CME*, Am. Med. Ass’n (Nov. 2011).

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

i. The Marketing Defendants Used “Branded” Advertising to Promote their Products to Doctors and Consumers

630. The Marketing Defendants engaged in widespread advertising campaigns touting the benefits of their branded drugs. The Marketing Defendants published print advertisements in a broad array of medical journals, ranging from those aimed at specialists, such as the *Journal of Pain* and *Clinical Journal of Pain*, to journals with wider medical audiences, such as the *Journal of the American Medical Association*. The Marketing Defendants collectively spent more than \$14 million on the medical journal advertising of opioids in 2011, nearly triple what they spent in 2001. The 2011 total includes \$8.3 million by Purdue, \$4.9 million by Janssen, and \$1.1 million by Endo.

631. The Marketing Defendants also targeted consumers in their advertising. They knew that physicians are more likely to prescribe a drug if a patient specifically requests it.²⁰⁴ They also knew that this willingness to acquiesce to such patient requests holds true even for opioids and for conditions for which they are not approved.²⁰⁵ Endo’s research, for example, also found that such communications resulted in greater patient “brand loyalty,” with longer durations of Opana ER therapy and fewer discontinuations. The Marketing Defendants thus increasingly took their opioid sales campaigns directly to consumers, including through patient-focused “education and support” materials in the form of pamphlets, videos, or other publications that patients could view in their physician’s office.

²⁰⁴ In one study, for example, nearly 20% of sciatica patients requesting oxycodone received a prescription for it, compared with 1% of those making no specific request. J.B. McKinlay *et al.*, *Effects of Patient Medication Requests on Physician Prescribing Behavior*, 52(2) Med. Care 294 (2014).

²⁰⁵ *Id.*

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

ii. The Marketing Defendants Used “Unbranded” Advertising to Promote Opioid Use for Chronic Pain Without FDA Review

632. The Marketing Defendants also aggressively promoted opioids through “unbranded advertising” to generally tout the benefits of opioids without specifically naming a particular brand-name opioid drug. Instead, unbranded advertising is usually framed as “disease awareness”—encouraging consumers to “talk to your doctor” about a certain health condition without promoting a specific product and, therefore, without providing balanced disclosures about the product’s limits and risks. In contrast, a pharmaceutical company’s “branded” advertisement that identifies a specific medication and its indication (i.e., the condition which the drug is approved to treat) must also include possible side effects and contraindications—what the FDA Guidance on pharmaceutical advertising refers to as “fair balance.” Branded advertising is also subject to FDA review for consistency with the drug’s FDA-approved label. Through unbranded materials, the Marketing Defendants expanded the overall acceptance of and demand for chronic opioid therapy without the restrictions imposed by regulations on branded advertising.

633. Many of the Marketing Defendants utilized unbranded websites to promote opioid use without promoting a specific branded drug, such as Purdue’s pain-management website, www.inthefaceofpain.com. The website contained testimonials from several dozen “advocates,” including health care providers, urging more pain treatment. The website presented the advocates as neutral and unbiased, but an investigation by the New York Attorney General later revealed that Purdue paid the advocates hundreds of thousands of dollars.

iii. The Marketing Defendants Funded, Edited and Distributed Publications That Supported Their Misrepresentations

634. The Marketing Defendants created a body of false, misleading, and unsupported medical and popular literature about opioids that (a) understated the risks and overstated the

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

benefits of long-term use; (b) appeared to be the result of independent, objective research; and (c) was likely to shape the perceptions of prescribers, patients, and payors. This literature served marketing goals, rather than scientific standards, and was intended to persuade doctors and consumers that the benefits of long-term opioid use outweighed the risks.

635. To accomplish their goal, the Marketing Defendants—sometimes through third-party consultants and/or Front Groups—commissioned, edited, and arranged for the placement of favorable articles in academic journals.

636. The Marketing Defendants' plans for these materials did not originate in the departments with the organizations that were responsible for research, development, or any other area that would have specialized knowledge about the drugs and their effects on patients; rather, they originated in the Marketing Defendants' marketing departments.

637. The Marketing Defendants made sure that favorable articles were disseminated and cited widely in the medical literature, even when the Marketing Defendants knew that the articles distorted the significance or meaning of the underlying study, as with the Porter & Jick letter. The Marketing Defendants also frequently relied on unpublished data or posters, neither of which are subject to peer review, but were presented as valid scientific evidence.

638. The Marketing Defendants published or commissioned deceptive review articles, letters to the editor, commentaries, case-study reports, and newsletters aimed at discrediting or suppressing negative information that contradicted their claims or raised concerns about chronic opioid therapy.

639. For example, in 2007 Cephalon sponsored the publication of an article titled "Impact of Breakthrough Pain on Quality of Life in Patients with Chronic, Noncancer Pain: Patient

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

Perceptions and Effect of Treatment with Oral Transmucosal Fentanyl Citrate,”²⁰⁶ published in the nationally circulated journal *Pain Medicine*, to support its effort to expand the use of its branded fentanyl products. The article’s authors (including Dr. Lynn Webster, discussed above) stated that the “OTFC [fentanyl] has been shown to relieve BTP more rapidly than conventional oral, normal-release, or ‘short acting’ opioids” and that “[t]he purpose of [the] study was to provide a qualitative evaluation of the effect of BTP on the [quality of life] of noncancer pain patients.” The number-one-diagnosed cause of chronic pain in the patients studied was back pain (44%), followed by musculoskeletal pain (12%) and head pain (7%). The article cites Portenoy and recommends fentanyl for non-cancer BTP patients:

In summary, BTP appears to be a clinically important condition in patients with chronic noncancer pain and is associated with an adverse impact on QoL. This qualitative study on the negative impact of BTP and the potential benefits of BTP-specific therapy suggests several domains that may be helpful in developing BTP-specific, QoL assessment tools.²⁰⁷

iv. The Marketing Defendants Used Detailing to Directly Disseminate Their Misrepresentations to Prescribers

640. The Marketing Defendants’ sales representatives executed carefully crafted marketing tactics, developed at the highest rungs of their corporate ladders, to reach targeted doctors with centrally orchestrated messages. The Marketing Defendants’ sales representatives also distributed third-party marketing material to their target audience that was deceptive.

641. Each Marketing Defendant promoted opioids through sales representatives (also called “detailers”) and, upon information and belief, small group speaker programs to reach out to individual prescribers. By establishing close relationships with doctors, the Marketing Defendants

²⁰⁶ Donald R. Taylor, et al., *Impact of Breakthrough Pain on Quality of Life in Patients With Chronic, Noncancer Pain: Patient Perceptions and Effect of Treatment With Oral Transmucosal Fentanyl Citrate (OTFC, ACTIQ)*, 8(3) *Pain Med.* 281-88 (Mar. 2007).

²⁰⁷ *Id.*

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

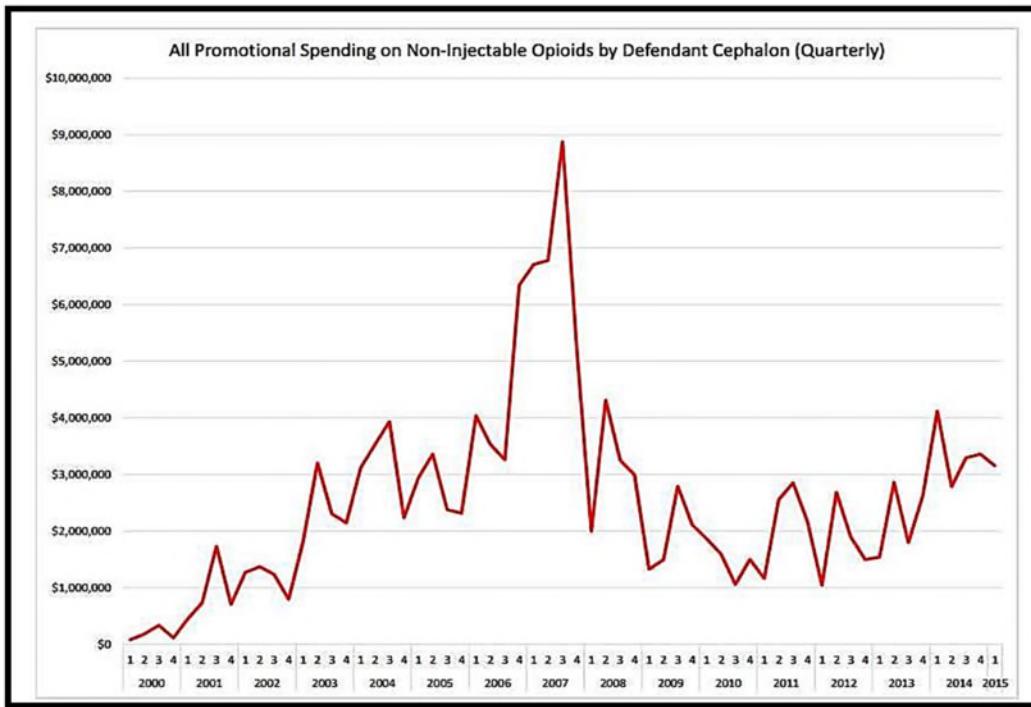
were able to disseminate their misrepresentations in targeted, one-on-one settings that allowed them to promote their opioids and to allay individual prescribers' concerns about prescribing opioids for chronic pain.

642. In accordance with common industry practice, the Marketing Defendants purchase and closely analyze prescription sales data from IMS Health (now IQVIA), a healthcare data collection, management and analytics corporation. This data allows them to track precisely the rates of initial and renewal prescribing by individual doctors, which allows them to target and tailor their appeals. Sales representatives visited hundreds of thousands of doctors and disseminated the misinformation and materials described above.

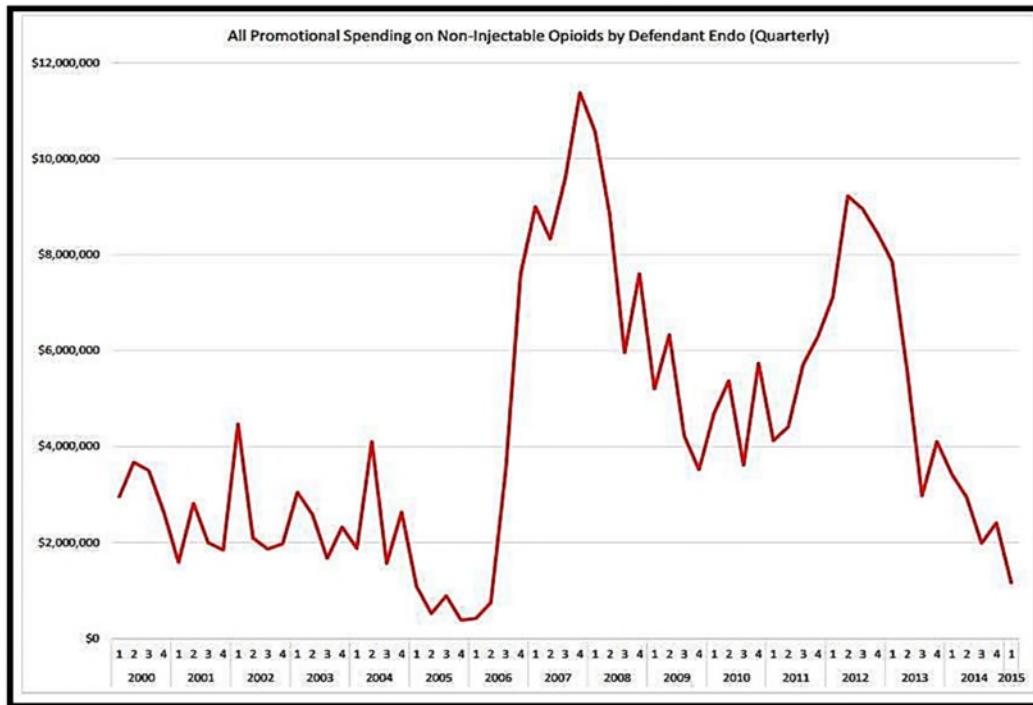
643. Marketing Defendants devoted and continue to devote massive resources to direct sales contacts with doctors. In 2014 alone, Marketing Defendants spent \$166 million on detailing branded opioids to doctors. This amount is twice as much as Marketing Defendants spent on detailing in 2000. The amount includes \$108 million spent by Purdue, \$34 million by Janssen, \$13 million by Teva, and \$10 million by Endo.

644. Cephalon's quarterly spending steadily climbed from below \$1 million in 2000 to more than \$3 million in 2014 (and more than \$13 million for the year), with a peak, coinciding with the launch of Fentora, of more than \$27 million in 2007, as shown below:

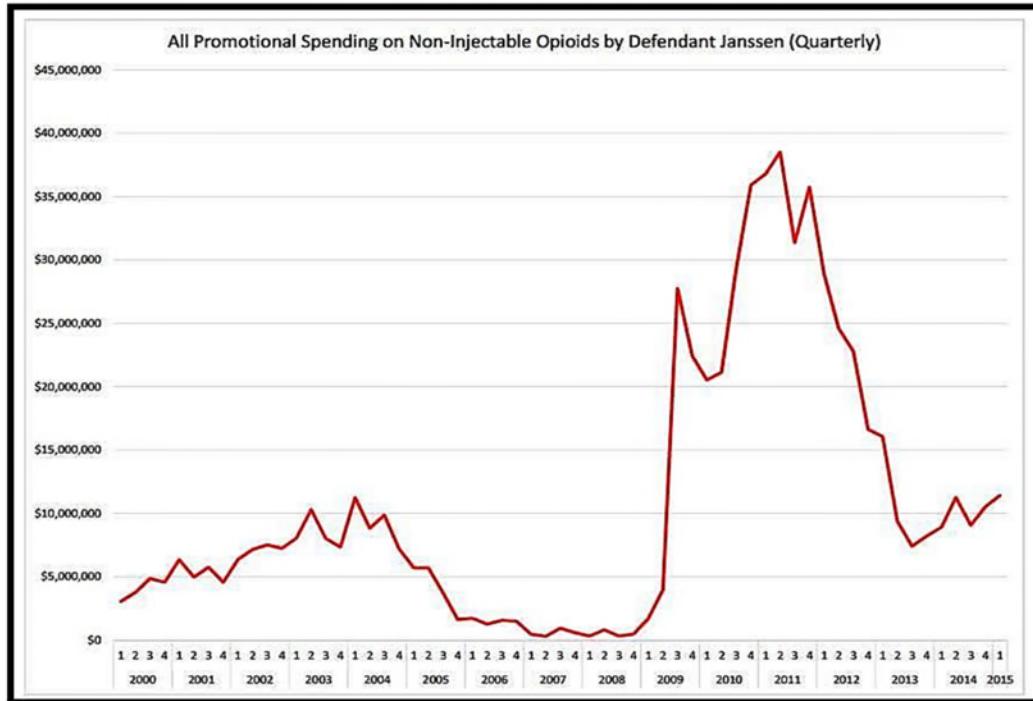
CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER



645. Endo's quarterly spending went from the \$2 million to \$4 million range in 2000-2004 to more than \$10 million following the launch of Opana ER in mid-2006 (and more than \$38 million for the year in 2007) and more than \$8 million coinciding with the launch of a reformulated version in 2012 (and nearly \$34 million for the year):

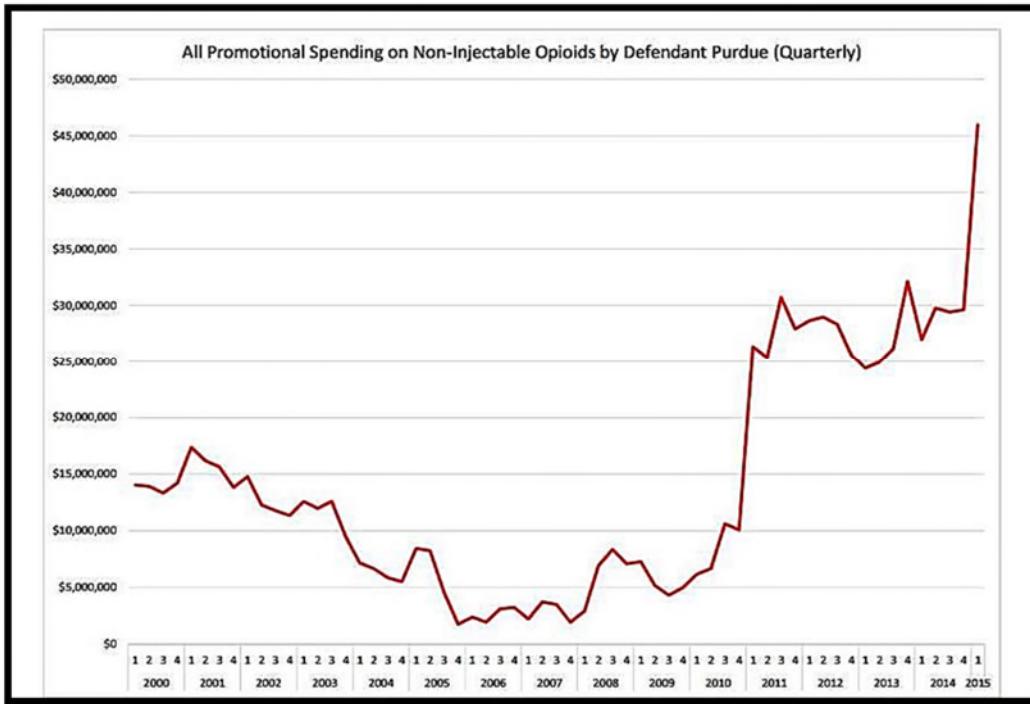
CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

646. Janssen's quarterly spending dramatically rose from less than \$5 million in 2000 to more than \$30 million in 2011, coinciding with the launch of Nucynta ER (with yearly spending at \$142 million for 2011), as shown below:



CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

647. Purdue's quarterly spending notably decreased from 2000 to 2007, as Purdue came under investigation by the Department of Justice, but then spiked to above \$25 million in 2011 (for a total of \$110 million that year), and continues to rise, as shown below:



648. For its opioid, Actiq, Cephalon also engaged in direct marketing in direct contravention of the FDA's strict instructions that Actiq be prescribed only to terminal cancer patients and by oncologists and pain management doctors experienced in treating cancer pain.

649. Thousands of prescribers attended Cephalon speaking programs. Cephalon tracked the impact that these programs had on prescribing in the three months following the event and concluded that doctors' prescribing of Fentora often increased.

v. Marketing Defendants Used Speakers' Bureaus and Programs to Spread Their Deceptive Messages.

650. In addition to making sales calls, Marketers' detailers also identified doctors to serve, for payment, on their speakers' bureaus and to attend programs with speakers and meals paid for by the Marketing Defendants. These speaker programs and associated speaker trainings

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

serve three purposes: they provide an incentive to doctors to prescribe, or increase their prescriptions of, a particular drug; to qualify to be selected a forum in which to further market to the speaker himself or herself; and an opportunity to market to the speaker's peers. The Marketing Defendants grade their speakers, and future opportunities are based on speaking performance, post-program sales, and product usage. Purdue, Janssen, Endo, Cephalon, and Mallinckrodt each made thousands of payments to physicians nationwide, for activities including participating on speakers' bureaus, providing consulting services, and other services.

3. The Marketing Defendants Targeted Vulnerable Populations

651. The Marketing Defendants specifically targeted their marketing at two vulnerable populations—the elderly and veterans.

652. Elderly patients taking opioids have been found to be exposed to elevated fracture risks, a greater risk for hospitalizations, and increased vulnerability to adverse drug effects and interactions, such as respiratory depression which occurs more frequently in elderly patients.

653. The Marketing Defendants promoted the notion—without adequate scientific foundation—that the elderly are particularly unlikely to become addicted to opioids. The AGS 2009 Guidelines, for example, which Purdue, Endo, and Janssen publicized, described the risk of addiction as “*exceedingly low* in older patients with no current or past history of substance abuse.” (emphasis added). As another example, an Endo-sponsored CME put on by NIPC, *Persistent Pain in the Older Adult*, taught that prescribing opioids to older patients carried “possibly less potential for abuse than in younger patients.” Contrary to these assertions, however, a 2010 study examining overdoses among long-term opioid users found that patients 65 or older were among those with the largest number of serious overdoses.

654. Similarly, Endo targeted marketing of Opana ER towards patients over 55 years old. Such documents show Endo treated Medicare part D patients among the “most valuable

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

customer segments.” However, in 2013, one pharmaceutical benefits management company recommended against the use of Opana ER for elderly patients and unequivocally concluded: “[f]or patients 65 and older these medications are not safe, so consult your doctor.”

655. According to a study published in the 2013 *Journal of American Medicine*, veterans returning from Iraq and Afghanistan who were prescribed opioids have a higher incidence of adverse clinical outcomes, such as overdoses and self-inflicted and accidental injuries. A 2008 survey showed that prescription drug misuse among military personnel doubled from 2002 to 2005, and then nearly tripled again over the next three years. Veterans are twice as likely as non-veterans to die from an opioid overdose.

656. Yet the Marketing Defendants deliberately targeted veterans with deceptive marketing. For example, a 2009 publication sponsored by Purdue, Endo, and Janssen, and distributed by APF with grants from Janssen and Endo, was written as a personal narrative of one veteran but was in fact another vehicle for opioid promotion. Called *Exit Wounds*, the publication describes opioids as “underused” and the “gold standard of pain medications” while failing to disclose significant risks of opioid use, including the risks of fatal interactions with benzodiazepines. According to a VA Office of Inspector General Report, 92.6% of veterans who were prescribed opioid drugs were also prescribed benzodiazepines, despite the increased danger of respiratory depression from the two drugs together.

657. Opioid prescriptions have dramatically increased for veterans and the elderly. Since 2007, prescriptions for the elderly have grown at twice the rate of prescriptions for adults between the ages of 40 and 59. And in 2009, military doctors wrote 3.8 million prescriptions for narcotic pain pills—four times as many as they did in 2001.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

4. The Marketing Defendants Had an Obligation to Educate Doctors to Prevent Future Harm

658. Even in the face of growing evidence of the overuse, abuse, addition to, and overdose from opioids, Marketing Defendants failed to take appropriate actions to protect public health and safety. Responsible companies marketing and selling highly addictive controlled substances would have, among other steps: (1) pulled in their marketing to avoid the overuse and oversupply of opioids; (2) ramped up efforts to detect, prevent, and address diversion and indications of improper or over-prescribing and dispensing; (3) ensured that doctors, pharmacists, and patients understood the appropriate use of opioids and accurately conveyed the risks and benefits of their drugs, correcting their years of misinformation. Using language identical to that approved by the FDA with respect to the brand-name labels, Marketing Defendants could have used the same mechanisms used to disseminate their fraudulent marketing-- CMES, speaker programs, sales representatives—among others, to stop the near-literal bleeding their promotional efforts had caused, and would continue to cause.

659. Instead of taking these steps, Marketing Defendants participated in an industry effort to water down a federally mandated REMS.

5. The Marketing Defendants' Scheme Succeeded, Creating a Public Health Epidemic

i. Marketing Defendants' dramatically expanded opioid prescribing and use.

660. The Marketing Defendants necessarily expected a return on the enormous investment they made in their deceptive marketing scheme, and worked to measure and expand their success. Their own documents show that they knew they were influencing prescribers and increasing prescriptions. Studies also show that in doing so, they fueled an epidemic of addiction and abuse.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

661. Endo, for example directed the majority of its marketing budget to sales representatives—with good results: 84% of its prescriptions were from the doctors they detailed. Moreover, as of 2008, cancer and post-operative pain accounted for only 10% of Opana ER’s uses; virtually all of Endo’s opioid sales—and profits—were from a market that did not exist ten years earlier. Internal emails from Endo staff attributed increases in Opana ER sales to the aggressiveness and persistence of sales representatives. Similarly, according to an internal Janssen training document, sales representatives were told that sales calls and call intensity have high correlation to sales.

662. Cephalon also recognized the return of its efforts to market Actiq and Fentora off-label for chronic pain. In 2000, Actiq generated \$15 million in sales. By 2002, Actiq sales had increased by 92%, which Cephalon attributed to “a dedicated sales force for ACTIQ” and “ongoing changes to [its] marketing approach including hiring additional sales representatives and targeting our marketing efforts to pain specialists.”²⁰⁸ Actiq became Cephalon’s second best-selling drug. By the end of 2006, Actiq’s sales had exceeded \$500 million. Only 1% of the 187,076 prescriptions for Actiq filled at retail pharmacies during the first six months of 2006 were prescribed by oncologists. One measure suggested that “more than 80 percent of patients who use[d] the drug don’t have cancer.”²⁰⁹

663. Upon information and belief, each of the Marketing Defendants tracked the impact of their marketing efforts to measure their impact in changing doctors’ perceptions and prescribing of their drugs. Their purchased prescribing and survey data that allowed them to closely monitor these trends, and they did actively monitor them. They monitored doctors’ prescribing before and

²⁰⁸ Cephalon, Inc. Annual Report (Form 10-K) at 28 (Mar. 31, 2003), <https://www.sec.gov/Archives/edgar/data/873364/000104746903011137/a2105971z10-k.htm>.

²⁰⁹ *Id.*

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

after detailing visits, and at various levels of detailing intensity, and before and after speaker programs, for instance. Defendants continued and, in many cases, expanded and refined their aggressive and deceptive marketing for one reason: it worked. As described in this Complaint, both in specific instances (e.g., the low abuse potential of various Defendants' opioids), and more generally, Defendants' marketing changed prescribers' willingness to prescribe opioids, lead them to prescribe more of their opioids, and persuaded them not to stop prescribing opioids or to switch to "safer" opioids, such as ADF.

664. This success would have come as no surprise. Drug company marketing materially impacts doctors' prescribing behavior. The effects of sales calls on prescribers' behavior is well documented in the literature, including a 2017 study that found that physicians ordered fewer promoted brand-name medications and prescribed more cost-effective generic versions if they worked in hospitals that instituted rules about when and how pharmaceutical sales representatives were allowed to detail prescribers. The changes in prescribing behavior appeared strongest at hospitals that implemented the strictest detailing policies and included enforcement measures. Another study examine four practices, including visits by sales representatives, medical journal advertisements, direct-to-consumer advertising, and pricing, and found that sales representatives have the strongest effect on drug utilization. An additional study found that doctor meetings with sales representatives are related to changes in both prescribing practices and requests by physicians to add the drugs to hospitals' formularies.

665. Marketing Defendants spent millions of dollars to market their drugs to prescribers and patients and meticulously tracked their return on that investment. In one recent survey published by the AMA, even though nine in ten general practitioners reported prescription drug abuse to be a moderate to large problem in their communities, 88% of the respondents said they

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

were confident in their prescribing skills, and nearly half were comfortable using opioids for chronic non-cancer pain. These results are directly due to the Marketing Defendants' fraudulent marketing campaign focused on several misrepresentations.

666. Thus, both independent studies and Defendants' own tracking confirm that Defendants' marketing scheme dramatically increased their sales.

ii. Marketing Defendants' deception in expanding their market created and fueled the opioid epidemic.

667. Independent research demonstrates a close link between opioid prescriptions and opioid abuse. For example, a 2007 study found "a very strong correlation between therapeutic exposure to opioid analgesics, as measured by prescriptions filled, and their abuse."²¹⁰ It has been estimated that 60% of the opioids that are abused come, directly or indirectly, through physicians' prescriptions.

668. There is a "parallel relationship between the availability of prescription opioid analgesics through legitimate pharmacy channels and the diversion and abuse of these drugs and associated adverse outcomes." The opioid epidemic is "directly related to the increasingly widespread misuse of powerful opioid pain medications."

669. In a 2016 report, the CDC explained that "[o]pioid pain reliever prescribing has quadrupled since 1999 and has increased in parallel with [opioid] overdoses." Patients receiving opioid prescriptions for chronic pain account for the majority of overdoses. For these reasons, the CDC concluded that efforts to rein in the prescribing of opioids for chronic pain are critical "to reverse the epidemic of opioid drug overdose deaths and prevent opioid-related morbidity."

²¹⁰ Theodore J. Cicero *et al.*, *Relationship Between therapeutic Use and Abuse of Opioid Analgesics in Rural, Suburban, and Urban Locations in the United States*, 16.8 *Pharmacopidemiology and Drug Safety*, 827-40 (2007).

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

F. The Supply Chain Defendants and National Pharmacies Deliberately Disregarded Their Duties to Maintain Effective Controls Against Diversion

670. The Supply Chain Defendants and National Pharmacies facilitated the supply of far more opioids that could have been justified to serve the legal and appropriate market. The failure of the Supply Chain Defendants and National Pharmacies to maintain effective controls, and of the Supply Chain Defendants to investigate, report, and take steps to halt orders that they knew or should have known were suspicious, breached both their statutory and common law duties.

671. For over a decade, the Supply Chain Defendants aggressively sought to bolster their revenue, increase profit, and grow their share of the prescription painkiller market by unlawfully and surreptitiously increasing the volume of opioids they sold. However, Supply Chain Defendants are not permitted to engage in a limitless expansion of their sales through the unlawful sales of regulated painkillers. Rather, as described below, Supply Chain Defendants are subject to various duties to prevent oversupply and diversion into the illicit market.

672. Supply Chain Defendants and National Pharmacies are all required to register as manufacturers, distributors, or dispensers pursuant to 21 U.S.C. § 823 and 21 C.F.R. §§ 1301.11, 1301.71.

673. As facilitated and caused by Supply Chain Defendants' and National Pharmacies' actions, opioids as a class of prescription drugs have skyrocketed. According to the CDC, opioid prescriptions, as measured by number of prescriptions and morphine milligram equivalent ("MME") per person, tripled from 1999 to 2015 nationally. The Department of Health and Human Services Estimates that, on an average day, more than 650,000 opioid prescriptions are dispensed in the U.S.

674. Multiple sources impose duties on the Supply Chain Defendants and National Pharmacies to maintain effective controls against diversion.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

675. First, under the common law, the Supply Chain Defendants had a duty to exercise reasonable care in manufacturing and distributing dangerous narcotic substances. National Pharmacies further had a duty to exercise reasonable care in supervising the sale of such drugs. By flooding West Virginia, Cabell County, and the City of Huntington with opioids and failing to effectively prevent diversion, including failing to monitor for red flags, Supply Chain Defendants and National Pharmacies breached their duties. By filling and failing to report or halt orders that they knew or should have realized were likely being diverted for illicit uses, Supply Chain Defendants further breached their duties. These breaches by the Supply Chain Defendants and National Pharmacies both created and failed to prevent a foreseeable risk of harm to the Plaintiffs and the Plaintiffs' Community.

676. Second, each of the Supply Chain Defendants and National Pharmacies was required to register with the DEA to manufacture and/or distribute and/or dispense controlled substances. *See* 21 U.S.C. § 823(a)-(b), (e); 28 C.F.R. § 0.100. As registrants, Supply Chain Defendants and National Pharmacies were required to "maintain effective controls and procedures" against diversion. 21 C.F.R. § 1301.71. Supply Chain Defendants and National Pharmacies have violated their duties arising from this federal law.

677. Third, Supply Chain Defendants and National Pharmacies also had, and violated, substantially similar duties under applicable West Virginia state laws.

678. Fourth, each of the Supply Chain Defendants and National Pharmacies assumed a duty, when speaking publicly about opioids and their efforts and commitment to combat diversion of prescription opioids, to speak accurately and truthfully.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER**1. ARCOS / DADS DATA**

679. The Automated Records and Consolidated Orders System/Diversion Analysis and Detection System (ARCOS/DADS)²¹¹ system is used to track and report the transfer of pharmaceuticals and to detect potential diversion. This system of records is maintained pursuant to the reporting requirements of the Comprehensive Drug Abuse Prevention and Control Act of 1970²¹² and to fulfill the United States treaty obligations under the Single Convention on Narcotic Drugs and the Convention on Psychotropic Substances of 1971.²¹³

680. All manufacturers and distributors of prescription opiates are required by federal law to report each transaction to a national database the ARCOS/DADS database.²¹⁴ This database can be used, along with other information, to identify unlawful sales of prescription opiates to every pill mill in America. However, the data has been concealed behind a curtain of "trade secret" until recently, when Pulitzer Prize winning journalist Eric Eyre gained access to the data in West Virginia.²¹⁵ The public disclosure of the West Virginia data initiated a Congressional investigation.

²¹¹ "ARCOS" refers to the automated, comprehensive drug reporting system which monitors the flow of DEA controlled substances from their point of manufacture through commercial distribution channels to point of sale or distribution at the dispensing/retail level - hospitals, retail pharmacies, practitioners, mid-level practitioners, and teaching institutions. Included in the list of controlled substance transactions tracked by ARCOS are the following: All Schedules I and II materials (manufacturers and distributors); Schedule III narcotic and gamma-hydroxybutyric acid (GHB) materials (manufacturers and distributors); and selected Schedule III and IV psychotropic drugs (manufacturers only). ARCOS accumulates these transactions which are then summarized into reports which give investigators in Federal and state government agencies information which can then be used to identify the diversion of controlled substances into illicit channels of distribution. The information on drug distribution is used throughout the United States (U.S.) by U.S. Attorneys and DEA investigators to strengthen criminal cases in the courts. *See* United States Department of Justice, Drug Enforcement Administration, Diversion Control Division, Automation of Reports and Consolidated Orders System (ARCOS), *Background: What is ARCOS and What Does it Do?*, <https://www.deadiversion.usdoj.gov/arcos/#background> (last visited September 7, 2017)

²¹² (21 U.S.C. 826(d))

²¹³ 69 FR 51104-02.

²¹⁴ DEA registrants are required by federal law to report records of sales of controlled substances with ARCOS/DADS. 21 C.F.R. 1304.33(c); 21 U.S.C. 827(d).

²¹⁵ Eric Eyre of Charleston Gazette-Mail, Charleston, WV, The 2017 Pulitzer Prize Winner in Investigative Reporting, available at <http://www.pulitzer.org/winners/eric-eyre> (last visited July 3, 2017); Eric Eyre, Drug firms poured 780M painkillers into WV amid rise of overdoses, Charleston Gazette-Mail, December 17, 2016, available at <http://www.wvgazettemail.com/news-health/20161217/drug-firms-poured-780m-painkillers-into-wv-amid-rise->

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

681. The data ultimately revealed through Mr. Eyre's efforts, shows limited but significant information about many of the Distributor Defendants' wrongful actions in the Plaintiffs' Community.

682. This information has become public knowledge as reported by the Charleston Gazette and reveals that drug wholesalers sold West Virginia pharmacies 780 million hydrocodone pills during this timeframe.²¹⁶ The records also disclose the number of hydrocodone doses sold to each of the 55 counties in West Virginia between 2007 and 2012. The data does not disclose the distributions per pharmacy nor the monthly shipments. Nonetheless, the data reveals that the Distributor Defendants sold some 23 million doses of hydrocodone to Cabell County pharmacies between 2007 and 2012. Specifically, the data reveals as follows the following about sales of a *single opioid* (hydrocodone) into Cabell County over a six-year period:

HYDROCODONE DISTRIBUTED INTO CABELL COUNTY 2007 – 2012								
Distributor Defendant	COUNTY	2007	2008	2009	2010	2011	2012	Grand Total
ABDC	CABELL	3,145,400	3,197,200	3,416,760	1,935,860	2,000,460	1,661,960	15,357,640
CVS	CABELL	916,400	979,500	1,084,200	1,037,400	1,225,500	1,315,300	6,558,300
CARDINAL	CABELL	250,720	206,600	236,540	1,467,690	1,287,750	1,183,320	4,632,620
RITE AID	CABELL	703,200	707,300	686,600	675,860	604,510	574,470	3,951,940
WAL-MART	CABELL	520,100	546,800	527,600	542,100	531,800	472,300	3,140,700
KROGER LP II	CABELL	0	142,040	644,920	604,640	571,260	467,230	2,430,090
McKESSON	CABELL	382,000	458,600	164,400	117,600	202,040	253,630	1,578,270
WALGREEN	CABELL	0	0	70,500	205,400	347,100	394,500	1,017,500
KROGER LP I	CABELL	484,500	422,900	0	0	4,500	0	911,900
H. D. SMITH	CABELL	0	53,550	301,430	0	0	14,800	369,780
TOTAL		6,404,327	6,716,498	7,134,959	6,588,560	6,776,931	6,339,522	39,948,740

of overdoses (last visited July 3, 2017); Subcommittee on Oversight and Investigations of the United States House of Representatives Energy and Commerce Committee outlined in the Letters to Distributors and the DEA Regarding Alleged Pill Dumping in West Virginia dated May 9, 2017 (available online).

²¹⁶ See Eric Eyre, Drug firms poured 780M painkillers into WV amid rise of overdoses, CHARLESTON GAZETTE (December 17, 2016).

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

683. ARCOS software enables the Drug Enforcement Administration (“DEA”) to maintain a current and historical record of selected controlled substance inventories and transactions from the point of manufacture to the point of sale, distribution, or other disposition, and finally, to the dispenser level.²¹⁷

684. The information contained in the ARCOS system consists of documentation of individual business transactions between individuals who handle controlled substances at every level, from manufacturers down to the pharmacies. Records include copies of controlled substances inventories, drug codes, deletion and adjustment reports, sales, and purchase orders, and includes, but not limited to the date of the transaction, the name, quantity, and quality of the chemicals/substances purchased or dispensed, the parties to the transaction, NCD code, and the DEA registrant numbers. This information provides an audit trail of all manufactured and/or imported controlled substances.

685. All automated data files associated with ARCOS/DADS are maintained in the Department of Justice Data Center and the Drug Enforcement Administration Data Center and the system is located at DEA, 700 Army Navy Drive, Arlington, VA 22202. 69 FR 51104-02.

686. The ARCOS/DADS system has access to all of the data submitted by each DEA registrant from across the country.²¹⁸ These distribution transactional records are compiled by the DEA through a portal and the data is compiled by DEA in accordance with law for determining

²¹⁷ See ARCOS Registrant Handbook, United States Department of Justice, Drug Enforcement Administration, Office of Diversion Control, Section 1.1.1, *ARCOS Defined* (Version 1.0 August 1997).

²¹⁸ The DEA maintains the Automation of Reports and Consolidated Orders System (“ARCOS”), an official automated comprehensive drug reporting system that monitors the flow of DEA controlled substances from their point of manufacture through commercial channels to the point of sale or distribution at the dispensing/retail level. Drug wholesalers do not have access to the ARCOS data or to the data of other wholesalers and distributors. *Keysource Med., Inc. v. Holder*, No. 1:11-CV-393, 2011 WL 3608097, at *2 (S.D. Ohio Aug. 16, 2011).

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

quota, distribution trends, internal audits, inspection, investigations and other analyses.²¹⁹

Additionally, the DEA provides internet access to summary data from this system.

687. Despite the fact reporting is mandated by Congress, and the database is maintained through taxpayer dollars, the DEA historically refuses to disclose the data.²²⁰ Nor have registrants, such as Cardinal Health, consented to its disclosure when requested.²²¹

688. Ironically, many distributors have complained to Congress and the federal courts that the DEA does not permit registrants to gain access to competitor data from ARCOS for purposes of ensuring a customer is not purchasing controlled substances from multiple suppliers. Yet, these same distributors sell their data through “chargebacks” to manufacturers. So too could they voluntarily shared data with each other or, simply, consent to disclosure.²²² Their hypocrisy knowing no bounds, the distributors opposed production of ARCOS data in this litigation²²³ yet argue the statute of limitations has expired and Plaintiffs knew or should have discovered the underlying misconduct giving rise to liability.

689. Each registrant has full visibility of its own controlled substance transactions, often down to the pharmacy, physician and patient level. DEA agent Gary Boggs, who was hired by McKesson, emphasized the importance of registrants knowing their own data, including ARCOS data, which may serve as an “early warning sign,” as well as relying on all available information to identify suspicious orders: not just relying on algorithms, like thresholds.²²⁴

²¹⁹ https://www.deadiversion.usdoj.gov/arcos/retail_drug_summary/index.html

²²⁰ See *Madel v. US Dep. of Justice*, 784 F.3d 448 (8th Cir. 2015).

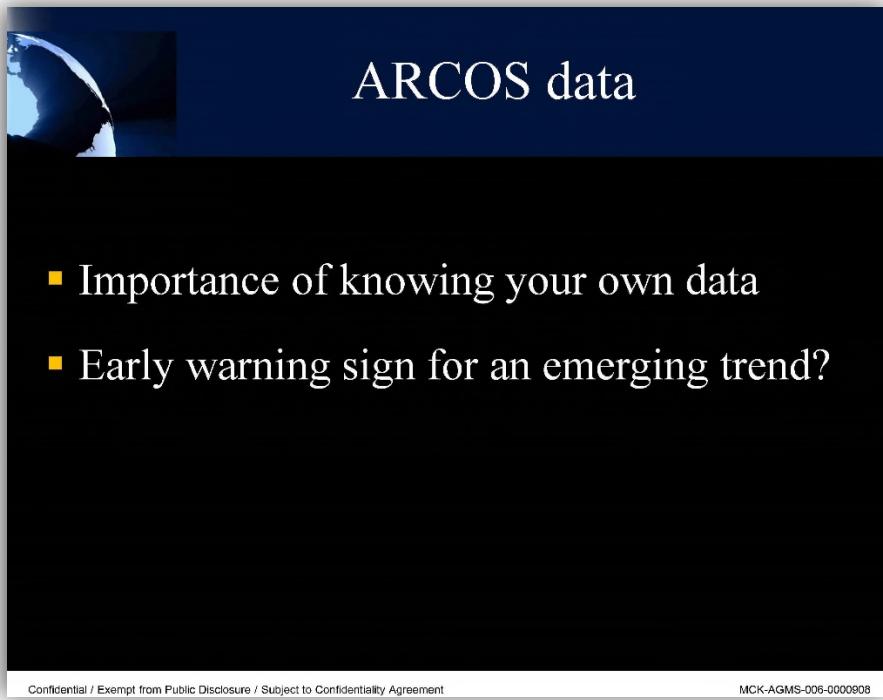
²²¹ See also Declaration of Tina Lantz, Cardinal Health VP of Sales Operation, *Madel v. USDOJ*, Case 0:13-cv-02832-PAM-FLN, (Document 93) (filed 11/02/16) (“Cardinal Health does not customarily release any of the information identified by the DEA notice letter to the public, nor is the information publicly available. Cardinal Health relies on DEA to protect its confidential business information reported to the Agency.”).

²²² 28 CFR § 16.7(e) [2015].

²²³ Plaintiffs served a *Touhy* request on the U.S. Dept. of Justice on October 2, 2017, in a companion case which was carried over to the docket once MDL2804 was formed. This Touhy request, and the subsequent pleadings, give rise to a court order mandating the DOJ disclose the ARCOS database to the Plaintiffs’ Executive Committee.

²²⁴ MCMKMDL00336833

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER



690. The MDL Plaintiffs' Executive Committee, on behalf of the MDL Plaintiffs, have procured the ARCOS database (2006-2014) and expended great resources to process the data into a useable format and performed analytics to understand and origins of the opioid epidemic. This dataset, which Plaintiffs believe will one day will be made public through the civil justice system, is relied upon herein and throughout this Complaint.

691. The ARCOS data reveals the extraordinary and escalating amounts of prescription opioids being sold into West Virginia and nationwide. Such excessive distribution was not supported by medical need or population growth and would not have happened, but for the Defendants' failures to fulfill their legal duties.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

2. As Registrants Under the Controlled Substances Act, Supply Chain Defendants and National Pharmacies Have a Duty to Maintain Effective Controls Against Diversion and Supply Chain Defendants Have a Duty to Detect, Report, and Halt Suspicious Orders.

692. Recognizing a need for greater scrutiny over controlled substances due to their potential for abuse and danger to public health and safety, the United States Congress enacted the Controlled Substances Act in 1970. The CSA and its implementing regulations created a closed system of distribution for all controlled substances and listed chemicals. Congress specifically designed the closed chain of distribution to prevent the diversion of legally produced controlled substances into the illicit market.

693. Congress was concerned with the diversion of drugs out of legitimate channels of distribution and acted to halt the “widespread diversion of [controlled substances] out of legitimate channels into the illegal market.” Moreover, the closed system was specifically designed to ensure that there are multiple ways of identifying and preventing diversion through active participation by registrants within the drug delivery chain.

694. All registrants – which includes all manufacturers, distributors, and dispensers of controlled substances – must adhere to the specific security, recordkeeping, monitoring and reporting requirements that are designed to identify or prevent diversion. When registrants at any level fail to fulfill their obligations, the necessary checks and balances collapse. The result is the scourge of addiction that has occurred.

695. The DEA has repeatedly, and unequivocally, emphasized:

- a. The purpose of the Controlled Substances Act and its federal regulations is to prevent diversion.
- b. Diversion is foreseeable if registrants fail to comply with federal law.
- c. Failure to comply with federal law enables more diversion.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

- d. The unlawful entry of more pills into the market results in more diversion.
- e. Diversion is detrimental to public health and safety.²²⁵

696. The Supply Chain Defendants' and National Pharmacies' legal duties with respect to controlled substances are set out under federal statutes, federal regulations, West Virginia state law (which incorporates federal law), and DEA guidance.

iii. Federal Statutory Duty

697. Supply Chain Defendants owe a duty to maintain effective controls and procedures against the diversion of prescription opiates into the illicit market.²²⁶

698. The Controlled Substances Act ("CSA") and its implementing regulations create restrictions on the distribution and dispensing of controlled substances.²²⁷

699. The main objectives of the CSA are to conquer drug abuse and to control the legitimate and illegitimate traffic in controlled substances. Congress was particularly concerned with the need to prevent the diversion of drugs from legitimate to illicit channels. To effectuate these goals, Congress devised a closed regulatory system making it unlawful to manufacture, distribute, dispense, or possess any controlled substance except in a manner authorized by the CSA. The CSA categorizes all controlled substances into five schedules. The drugs are grouped together based on their accepted medical uses, the potential for abuse, and their psychological and physical effects on the body. Each schedule is associated with a distinct set of controls regarding the manufacture, distribution, and use of the substances listed therein. The CSA and its

²²⁵ See Prevoznik Dep. Vol. II, 638:9 to 647:14, April 18, 2019 (DEA 30(b)(6) designee).

²²⁶ 21 U.S.C.A. § 823(b)(1); 21 U.S.C. § 802(10); 21 U.S.C. § 822(a)(2)); and 21 C.F.R. § 1301.71.

²²⁷ See 21 U.S.C. §§ 801–971 (2006); 21 C.F.R. §§ 1300–1321 (2009).

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

implementing regulations set forth strict requirements regarding registration, labeling and packaging, production quotas, drug security, and recordkeeping.²²⁸

700. The CSA authorizes the DEA to establish a registration program for manufacturers, distributors, and dispensers of controlled substances designed to prevent the diversion of legally produced controlled substances into the illicit market.²²⁹ Any entity that seeks to become involved in the production or chain of distribution of controlled substances must first register with the DEA.²³⁰

701. The CSA provides for control by the Justice Department of problems related to drug abuse through registration of manufacturers, wholesalers, retailers, and all others in the legitimate distribution chain, and makes transactions outside the legitimate distribution chain illegal.²³¹

702. “Congress was particularly concerned with the diversion of drugs from legitimate channels. It was aware that registrants, who have the greatest access to controlled substances and therefore the greatest opportunity for diversion, were responsible for a large part of the illegal drug traffic.”²³²

703. The CSA is “[d]esigned to improve the administration and regulation of the manufacturing, distribution, and dispensing of controlled substances by providing for a ‘closed’ system of drug distribution for legitimate handlers of such drugs. Such a closed system is intended to reduce the widespread diversion of these drugs out of legitimate channels into the illicit market,

²²⁸ *Gonzales v. Raich*, 545 U.S. 1, 12–14 (2005) (internal citations omitted).

²²⁹ H.R. Rep. No. 91-1444, 1970 U.S.C.C.A.N. 4566, 4572 (Sept. 10, 1970); *see* 21 U.S.C. § 801(2); 21 U.S.C. §§ 821-824, 827, 880.

²³⁰ 21 U.S.C. § 822; 21 C.F.R. § 1301.11.

²³¹ 1970 U.S.C.C.A.N. 4566, 4569 (emphasis added).

²³² *United States v. Moore*, 423 U.S. 122, 135 (1975).

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

while at the same time providing the legitimate drug industry with a unified approach to narcotic and dangerous drug control.”²³³

iv. Federal Regulatory Duty

704. Supply Chain Defendants and National Pharmacies owe a regulatory duty to “provide effective controls and procedures to guard against theft and diversion of controlled substances”²³⁴ by, *inter alia*, developing and implementing a system to identify and report suspicious prescriptions based on known red flags, such as pattern prescriptions like the same types of drugs in the same quantities from the same prescriber.²³⁵

705. Supply Chain Defendants must also “design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.”²³⁶ This nonexclusive definition of “suspicious order” has been codified in the CSA.²³⁷ Other red flags indicating suspicion may include, for example, “[o]rdering the same controlled substance from multiple distributors.”²³⁸

706. These criteria for identifying suspicious orders are disjunctive and are not all inclusive. For example, if an order deviates substantially from a normal pattern, the size of the order does not matter and the order should be reported as suspicious. Likewise, a registrant need

²³³ 1970 U.S.C.C.A.N. 4566, 4571-72.

²³⁴ 21 C.F.R. § 1301.71(a).

²³⁵ See, e.g., *Holiday CVS, L.L.C., d/b/a CVS/Pharmacy Nos. 219 and 5195*; Decision and Order, 77 FR 62316-01 (Oct. 12, 2012) (noting that certain red flags, such as “the red flags presented by the circumstances of patients travelling from Kentucky or Tennessee to South Florida to obtain prescriptions, including for a schedule II narcotic, which by definition has the highest potential for abuse of any drug that may be prescribed lawfully, see 21 U.S.C. 812(b)(2), and then travelling to Respondents to fill them, are so obvious that only those who are deliberately ignorant would fill these prescriptions.”).

²³⁶ 21 C.F.R. § 1301.74(b) [1971].

²³⁷ 21. U.S.C. § 802. Definitions, 21 USCA § 802

²³⁸ 21 C.F.R. § 1301.74(b) [1971].

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

not wait for a normal pattern to develop over time before determining whether a particular order is suspicious. The size of an order alone, regardless of whether it deviates from a normal pattern, is enough to trigger the responsibility to report the order as suspicious. The determination of whether an order is suspicious depends not only on the ordering patterns of the particular customer but also on the patterns of the entirety of the customer base and the patterns throughout the relevant segment of the industry. For this reason, identification of suspicious orders serves also to identify excessive volume of the controlled substance being shipped to a particular region.

707. This regulatory duty has been defined to include the following obligations:

The “**security requirement**” at the heart of this case mandates that distributors “design and operate a system” to identify “suspicious orders of controlled substances” and report those orders to DEA (the **Reporting Requirement**). 21 C.F.R. § 1301.74(b). The Reporting Requirement is a relatively modest one: It requires only that a distributor [or other registrant] provide basic information about certain orders to DEA, so that DEA “investigators in the field” can aggregate reports from every point along the legally regulated supply chain and use the information to ferret out “potential illegal activity.” *Southwood Pharm., Inc.*, 72 Fed. Reg. 36,487, 36,501 (Drug Enf’t Admin. July 3, 2007). Once a distributor [or other registrant] has reported a suspicious order, it must make one of two choices: decline to ship the order, or conduct some “due diligence” and—if it is able to determine that the order is not likely to be diverted into illegal channels—ship the order (the **Shipping Requirement**).²³⁹

708. Of course, a registrant’s due diligence efforts must be thorough: “the investigation must dispel all red flags indicative that a customer is engaged in diversion to render the order non-suspicious and exempt it from the requirement that the distributor ‘inform’ the Agency about the order. Put another way, if, even after investigating the order, there is any remaining basis to suspect that a customer is engaged in diversion, the order must be deemed suspicious and the Agency must be informed.”²⁴⁰ Indeed, the DEA may revoke a distributor’s certificate of registration as a vendor

²³⁹ *Masters Pharm., Inc. v. Drug Enf’t Admin.*, 861 F.3d 206, 212–13 (D.C. Cir. 2017) (emphasis added).

²⁴⁰ *Masters Pharmaceuticals, Inc.*, Decision and Order, 80 Fed. Reg. 55418-01 at *55477 (DEA Sept. 15, 2015).

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

of controlled substances if the distributor identifies orders as suspicious and then ships them “without performing adequate due diligence.”²⁴¹

709. The DEA has testified that:

- a. DEA registrants are required to block all suspicious orders prescription opioids.²⁴²
- b. Shipping a suspicious order is a per se violation of federal law.²⁴³
- c. If a wholesale distributor blocks a suspicious order, they should terminate all future sales to that same customer until they can rule out that diversion is occurring.²⁴⁴
- d. After the fact reporting of suspicious orders has never been in compliance with federal law.²⁴⁵

v. DEA Guidance

710. The DEA has repeatedly reminded the Supply Chain and National Pharmacy Defendants of their regulatory obligations. For example, in responding to the proliferation of pharmacies operating on the internet that arranged illicit sales of enormous volumes of opioids to drug dealers and customers, the DEA began a major push to remind distributors of their obligations to prevent these kinds of abuses by educating them on their duties to report and decline to fill suspicious orders. Since 2007, the DEA has hosted at least five conferences that provided registrants with updated information about diversion trends and regulatory changes. Many of the Manufacturer Defendants and the majority of the Distributor Defendants, if not all of them,

²⁴¹ *Masters Pharmaceuticals*, 861 F.3d at 212. “The *Decision and Order* was a final order entered by the DEA revoking Masters Pharmaceutical’s certificate of registration, without which Masters Pharmaceutical could not sell controlled substances. In *Masters Pharmaceutical*, the D.C. Circuit Court of Appeals denied a petition for review, leaving intact the DEA’s analysis and conclusion in the *Decision and Order*.²⁴²”

²⁴² See Prevosnik Dep. Vol II, 770:6 to 771:20, April 18, 2019 (DEA 30(b)(6) designee).

²⁴³ *Id.* at 632:7 to 633:2.

²⁴⁴ *Id.* at 628:24 to 629:15.

²⁴⁵ *Id.* at 673:7 to 674:13 , 679:20 to 680:8.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

attended at least one of these conferences. The DEA has also briefed wholesalers regarding legal, regulatory, and due diligence responsibilities since 2006. During these briefings, the DEA pointed out the red flags wholesale distributors should look for to identify potential diversion.²⁴⁶

711. In a September 27, 2006 letter, the DEA also reminded every commercial entity registered to distribute controlled substances that they are “one of the key components of the distribution chain. If the closed system is to function properly . . . distributors must be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes. This responsibility is critical, as . . . the illegal distribution of controlled substances has a substantial and detrimental effect on the health and general welfare of the American people.” The DEA’s September 27, 2006 letter also expressly reminded them that registrants, in addition to reporting suspicious orders, have a “statutory responsibility to exercise due diligence to avoid filling suspicious orders that might be diverted into other than legitimate medical, scientific, and industrial channels.” The same letter reminds distributors of the importance of their obligation to “be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes,” and warns that “even just one distributor that uses its DEA registration to facilitate diversion can cause enormous harm.”

712. The DEA sent another letter to all entities registered to distribute or manufacture controlled substances on December 27, 2007, reminding them that, as registered manufacturers and distributors of controlled substances, they share, and must each abide by, statutory and regulatory duties to “maintain effective controls against diversion” and “design and operate a system to disclose to the registrant suspicious orders of controlled substances.” The DEA’s

²⁴⁶ See, e.g., Presentation from August 23, 2005 Meeting with Cardinal Health, US-DEA-00000352 (noting that red flags to consider include frequency of orders, size of orders, range of products purchased, payment method, pharmacy location, and percentage of controlled to non-controlled substances ordered).

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

December 27, 2007 letter reiterated the obligation to detect, report, and not fill suspicious orders and provided detailed guidance on what constitutes a suspicious order and how to report (e.g., by specifically identifying an order as suspicious, not merely transmitting data to the DEA). The letter explains:

The regulation also requires that the registrant inform the local DEA Division Office of suspicious orders when discovered by the registrant. Filing a monthly report of completed transactions (e.g., “excessive purchase report” or “high unity purchases”) does not meet the regulatory requirement to report suspicious orders. Registrants are reminded that their responsibility does not end merely with the filing of a suspicious order report. Registrants must conduct an independent analysis of suspicious orders prior to completing a sale to determine whether the controlled substances are likely to be diverted from legitimate channels. Reporting an order as suspicious will not absolve the registrant of responsibility if the registrant knew, or should have known, that the controlled substances were being diverted.

The regulation specifically states that suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of an unusual frequency. These criteria are disjunctive and are not all inclusive. For example, if an order deviates substantially from a normal pattern, the size of the order does not matter and the order should be reported as suspicious. Likewise, a registrant need not wait for a “normal pattern” to develop over time before determining whether a particular order is suspicious. The size of an order alone, whether or not it deviates from a normal pattern, is enough to trigger the registrant’s responsibility to report the order as suspicious. The determination of whether an order is suspicious depends not only on the ordering patterns of the particular customer, but also on the patterns of the registrant’s customer base and the pattern throughout the segment of the regulated industry.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

Registrants that rely on rigid formulas to define whether an order is suspicious may be failing to detect to suspicious orders. For example, a system that identifies orders as suspicious only if the total amount of a controlled substance ordered during one month exceeds the amount ordered the previous month by a certain percentage or more is insufficient. This system fails to identify orders placed by a pharmacy if the pharmacy placed unusually large orders from the beginning of its relationship with the distributor. Also, this system would not identify orders as suspicious if the order were solely for one highly abused controlled substance if the orders never grew substantially. Nevertheless, ordering one highly abused controlled substance and little or nothing else deviates from the normal pattern of what pharmacies generally order.

When reporting an order as suspicious, registrants must be clear in their communication with DEA that the registrant is actually characterizing an order as suspicious. Daily, weekly, or monthly reports submitted by registrant indicating “excessive purchases” do not comply with the requirement to report suspicious orders, even if the registrant calls such reports “suspicious order reports.”

Lastly, registrants that routinely report suspicious orders, yet fill these orders without first determining that order is not being diverted into other than legitimate medical, scientific, and industrial channels, may be failing to maintain effective controls against diversion. Failure to maintain effective controls against diversion is inconsistent with the public interest as that term is used in 21 USC 823 and 824, and may result in the revocation of the registrant’s DEA Certificate of Registration.

713. Finally, the letter references the Revocation of Registration issued in *Southwood Pharmaceuticals, Inc.*, 72 Fed. Reg. 36,487-01 (July 3, 2007), which discusses the obligation to report suspicious orders and “some criteria to use when determining whether an order is suspicious.”

714. The DEA has emphasized that manufacturers also have a duty to report suspicious orders, as plainly stated in the statutes and regulations. This duty was recently reaffirmed when, in 2017, Mallinckrodt was fined \$35 million for failing to report suspicious orders of controlled substances and for violating recordkeeping requirements. In the press release accompanying the

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

settlement, the Department of Justice stated that Mallinckrodt “did not meet its obligations to detect and notify DEA of suspicious orders of controlled substances” and noted that “[m]anufacturers and distributors have a crucial responsibility to ensure that controlled substances do not get into the wrong hands.”

715. The DEA has also repeatedly emphasized that retail pharmacies, including the National Pharmacies, are required to implement systems that detect and prevent diversion and must monitor for red flags of diversion. For example, in a 2016 presentation to the American Pharmacists Association, the DEA reiterated that retail pharmacies must watch for red flags such as: large numbers of customers who: receive the same combination of prescriptions, receive the same strength of controlled substance prescription (often for the strongest dose), have prescriptions from the same prescriber, and have the same diagnosis code.²⁴⁷ The DEA has also conducted meetings with retail pharmacies, including the National Pharmacies. For example, in December 2010, DEA hosted a meeting with CVS’s representatives and counsel and advised CVS of the “red flags . . . that a pharmacy should be familiar with in order to carry out its corresponding responsibility to ensure that the controlled substances are dispensed for a legitimate medical purpose.”²⁴⁸

716. Examples of red flags that the DEA identified during its meeting with CVS include:

- a. many customers receiving the same combination of prescriptions (*i.e.*, oxycodone and alprazolam);
- b. many customers receiving the same strength of controlled substances (*i.e.*, 30 milligrams of oxycodone with 15 milligrams of oxycodone and 2 milligrams of alprazolam);

²⁴⁷ CAH_MDL2804_00041751

²⁴⁸ Declaration of Joe Rannazzisi Decl. in Holiday CVS, L.L.C. v. Holder, 839 F.Supp.2d 145 (D.D.C. 2012).

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

- c. many customers paying cash for their prescriptions; (d) many customers with the same diagnosis codes written on their prescriptions (*i.e.*, back pain, lower lumbar, neck pain, or knee pain);
- d. individuals driving long distances to visit physicians and/or to fill prescriptions.²⁴⁹

vi. Duties pursuant to West Virginia Law

717. The conduct of the Supply Chain and National Pharmacy Defendants constitutes a violation of the Defendants' duties pursuant to both federal and West Virginia law.

718. In the sale and distribution of opioids in West Virginia and Plaintiffs' Community, Supply Chain and National Pharmacy Defendants violated their duties under federal law, including, but not limited to, 21 U.S.C.A. § 823 and 21 C.F.R. § 1301.71-74, and West Virginia law, including, but not limited to W. Va. Code § 60A-8-7(c)(1)(I); W. Va. Code § 60A-8-7(c)(3); W. Va. C.S.R. § 15-2-5 (previously W. Va. C.S.R. § 15-2-4). The aforesaid statutes and regulations are public safety statutes and regulations.

719. The West Virginia Legislature enacted the West Virginia Wholesale Drug Distribution Licensing Act of 1991 ("DDLA"), W. Va. Code § 60A-8-1 et seq. [1991], to protect the health, safety, and general welfare of residents of this state and authorized that the board of pharmacy shall promulgate rules to carry out its purpose.

720. The West Virginia Board of Pharmacy was granted the power to promulgate rules "as may be necessary to carry out the purposes and enforce the provisions of the DDLA which "shall conform to wholesale drug distributor licensing guidelines formally adopted by the food and drug administration at 21 C.F.R. Part 205." See W. Va. Code § 60A-8-9.

²⁴⁹ *Id.*

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

721. The West Virginia DDLA OF 1991 defines “Wholesale drug distributor” and “wholesale distributor” to mean any “entity engaged in wholesale distribution of prescription drugs, including, but not limited to manufacturers, ... brokers, warehouses, including manufacturers’ and distributors’ warehouses, chain drug warehouses and wholesale drug warehouses, ... retail and hospital pharmacies that conduct wholesale distributions, including but not limited to, any pharmacy distributor” W. Va. Code § 60A-8-5(b).

722. The West Virginia DDLA defines “pharmacy distributor” as “any pharmacy licensed in this state or hospital pharmacy which is engaged in the delivery or distribution of prescription drugs either to any other pharmacy licensed in this state or to any other person or entity, including, but not limited to, a wholesale drug distributor ... engaged in the delivery or distribution of prescription drugs and who is involved in the actual, constructive or attempted transfer of a drug in this state to other than the ultimate consumer except as otherwise provided for by law.” W. Va. Code § 60A-8-5(c).

723. The West Virginia DDLA of 1991 defines “manufacturer” as “any person who is engaged in manufacturing, preparing, propagating, compounding, processing, packaging, repackaging or labeling of a prescription drug, whether within or outside this state.” W. Va. Code § 60A-8-5(d).

724. The Rules of the Board of Pharmacy for the Uniform Controlled Substances Act are codified in W.Va. C.S.R. § 15-2-1 *et seq.*

725. The West Virginia Uniform Controlled Substance Act requires “every person who manufactures, distributes, or dispenses any controlled substance within this state” to “obtain annually a registration issued by the state board of pharmacy.” W. Va. Code § 60A-3-302(a); see also W.Va. C.S.R. § 15-2-4 (previously W.Va. C.S.R. § 15-2-3).

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

726. All of the Supply Chain Defendants meet were thus required to be licensed by the West Virginia Board of Pharmacy and adhere to the regulations.

727. The West Virginia Board of Pharmacy has adopted, by reference, the requirements of the federal regulations, 21 CFR Parts 1300-1321, and 21 U.S.C. 801. W. Va. C.S.R. § 15-2-3 (previously W. Va. C.S.R. § 15-2-2).

728. West Virginia state law expressly imposes a duty upon the Supply Chain Defendants and National Pharmacies to provide effective controls and procedures to guard against theft and diversion of controlled substances. W. Va. C.S.R. § 15-2-5.1.1 (previously W. Va. C.S.R. § 15-2-4.2.1).

729. The Supply Chain Defendants and National Pharmacies had a duty not to breach the standard of care established under West Virginia law and regulations and the CSA and its implementing regulations to provide effective controls and procedures to guard against theft and diversion of controlled substances. W. Va. C.S.R. § 15-2-5.1.1 (previously W. Va. C.S.R. § 15-2-4.2.1).

730. West Virginia state law further imposes a duty upon the Supply Chain Defendants to design and operate a system to disclose to the registrant suspicious orders of controlled substances and inform the West Virginia Board of Pharmacy of suspicious orders when discovered “by providing a copy of the information which the wholesale drug distributor provides to the U.S. Drug Enforcement Administration regarding such suspicious orders.” W. Va. C.S.R. § 15-2-5.3 (previously W. Va. C.S.R. § 15-2-4.4). Suspicious orders include “orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.” *Id.*

731. The Supply Chain Defendants had a duty not to breach the standard of care established under West Virginia law and regulations and the CSA and its implementing regulations

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

to report suspicious prescribing and to maintain systems to detect and report such activity. See 21 U.S.C. §823; 21 C.F.R. 1301.74; W. Va. C.S.R. § 15-2-5 (previously W. Va. C.S.R. § 15-2-4).

732. Each Defendant was required under West Virginia law to first be licensed by the West Virginia State Board of Pharmacy. W. Va. Code § 60A-8-7. To receive and maintain their license, each of the Distributor Defendant has a duty to comply with federal, state, and local laws regarding the distribution of drugs. W. Va. Code § 60A-8-7(c)(1)(I); *see also* W. Va. Code § 60A-8-7(c)(3) (requiring compliance with guidelines adopted by the United States Food and Drug Administration).

733. The West Virginia State Board of Pharmacy has the authority to suspend or revoke licenses or registrations issued to Wholesale Drug Distributors who violate Board of Pharmacy regulations. W. Va. Code § 60A-8-10(c).

734. Federal and West Virginia laws and regulations require Supply Chain Defendants to act as gatekeepers guarding against the diversion of the highly addictive, dangerous opioid drugs. See 21 U.S.C. § 823; 21 C.F.R. 1301.74; W. Va. C.S.R. § 15-2-5 (previously W. Va. C.S.R. § 15-2-4).

3. Supply Chain Defendants and National Pharmacies Have a Duty to Apply their Specialized Knowledge of the Market to Prevent Diversion

735. As set forth above, Supply Chain Defendants and National Pharmacies have several responsibilities under state and federal law with respect to control of the supply chain of opioids. First, they must design and operate a system that detects and stops suspicious transactions by, among other things, reviewing and analyzing their own data, relying on their observations of prescribers and pharmacies, and following up on reports or concerns of potential diversion. Further, with regard to Supply Chain Defendants, all suspicious orders must be reported to relevant enforcement authorities and shipment of any order which is flagged as suspicious must be stopped.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

Supply Chain Defendants can only ship orders which were flagged as potentially suspicious if, after conducting due diligence, they can determine that the order is not likely to be diverted into illegal channels.

736. State and federal statutes and regulations reflect a standard of conduct and care below which reasonably prudent registrants would not fall. Together, these laws and industry guidelines make clear that all Supply Chain Defendants and National Pharmacies possess and are expected to possess specialized and sophisticated knowledge, skill, information, and understanding of both the market for scheduled prescription narcotics and of the risks and dangers of the diversion of prescription narcotics when the supply chain is not properly controlled.

737. Further, these laws and industry guidelines make clear that the Supply Chain Defendants and National Pharmacies have a duty and responsibility to exercise the specialized and sophisticated knowledge, information, skill, and understanding they possess by virtue of their role in the supply chain to prevent the oversupply of prescription opioids and minimize the risk of their diversion into an illicit market.

738. For example, both because distributors handle such large volumes of controlled substances, and because they are “uniquely positioned,” based on their knowledge of their customers and orders, as the first line of defense in the movement of legal pharmaceutical controlled substances from legitimate channels into the illicit market, a distributors’ obligation to maintain effective controls to prevent diversion of controlled substances is critical. Should a distributor deviate from these checks and balances, the closed system of distribution, designed to prevent diversion, collapses.

739. The FTC has recognized the unique role of distributors. Since their inception, distributors have continued to integrate vertically by acquiring businesses that are related to the

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

distribution of pharmaceutical products and health care supplies. In addition to the actual distribution of pharmaceuticals, as wholesalers, distributors also offer their pharmacy, or dispensing, customers a broad range of added services. For example, distributors offer their pharmacies sophisticated ordering systems and access to an inventory management system and distribution facility that allows customers to reduce inventory carrying costs. Distributors are also able to use the combined purchase volume of their customers to negotiate the cost of goods with manufacturers and offer services that include software assistance and other database management support.²⁵⁰ As a result of their acquisition of a diverse assortment of related businesses within the pharmaceutical industry, as well as the assortment of additional services they offer, distributors have a unique insight into the ordering patterns and activities of their dispensing customers.

740. Manufacturers also have specialized and detailed knowledge of the potential suspicious prescribing and dispensing of opioids through their regular visits to doctors' offices and pharmacies, and from the data they purchase from commercial sources, such as IMS Health (now IQVIA). Their extensive boots-on-the-ground through their sales force, allows Manufacturer Defendants to observe the signs of suspicious prescribing and dispensing discussed elsewhere in the Complaint—lines of seemingly healthy patients, out-of-state license plates, and cash transactions, to name only a few. In addition, Manufacturer Defendants regularly mine data, including, upon information and belief, chargeback data, that allows them to monitor the volume and type of prescribing of doctors, including sudden increases in prescribing and unusually high dose prescribing, that would have alerted them, independent of their sales representatives, to suspicious prescribing. Manufacturers also have access to significant data through their

²⁵⁰ See *Fed. Trade Comm'n v. Cardinal Health, Inc.*, 12 F. Supp. 2d 34, 41 (D.D.C. 1998) (granting the FTC's motion for preliminary injunction and holding that the potential benefits to customers did not outweigh the potential anti-competitive effect of a proposed merger between Cardinal Health, Inc. and Bergen Brunswig Corp.).

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

procurement of “chargeback data,” as discussed further herein. These information points give Manufacturer Defendants insight into prescribing and dispensing conduct that enables them to play a valuable role in the preventing diversion and fulfilling their obligations under the CSA.

741. In connection with its recent 2017 settlement with the DEA, Mallinckrodt stated that it “recognizes the importance of the prevention of diversion of the controlled substances they manufacture” and agreed that it would “design and operate a system that meets the requirements of 21 CFR 1301.74(b) . . . [such that it would] utilize all available transaction information to identify suspicious orders of any Mallinckrodt product.” Mallinckrodt specifically agreed “to notify DEA of any diversion and/or suspicious circumstances involving any Mallinckrodt controlled substances that Mallinckrodt discovers.”

742. Moreover, Mallinckrodt acknowledged that “[a]s part of their business model Mallinckrodt collects transaction information, referred to as chargeback data, from the direct customer sales of controlled substances to ‘downstream’ registrants.”²⁵¹ This exchange of information, upon information, and belief, would have opened channels providing for the exchange of information revealing suspicious orders as well. The practice of obtaining “chargeback” data should have enabled Mallinckrodt not only to see red flags in the orders it filled itself as a wholesaler, but also additional red flags from the added data it received from its distributor customers.

743. As part of the settlement, Mallinckrodt agreed that it could and would “report to the DEA when Mallinckrodt concludes that the chargeback data or other information indicates that a downstream registrant poses a risk of diversion.”

²⁵¹ Administrative Memorandum of Agreement between the United States Department of Justice, the Drug Enforcement Agency, and Mallinckrodt, plc. and its subsidiary Mallinckrodt, LLC at 5 (July 10, 2017), <https://www.justice.gov/usao-edmi/press-release/file/986026/download>. (“2017 Mallinckrodt MOA”).

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

744. The DEA has also repeatedly affirmed the obligations of National Pharmacies to maintain effective controls against diversion in regulatory action after regulatory action.²⁵² Not only do National Pharmacies often have firsthand knowledge of dispensing red flags – such as disparate geographic location of doctors from the pharmacy or customer, lines of seemingly healthy patients, out-of-state license plates, and cash transactions, and other significant information – but also, the National Pharmacies have the ability to analyze data relating to drug utilization and prescribing patterns across multiple retail stores. Like the Distributor Defendants and Manufacturer Defendants, these information points give the National Pharmacies insight into prescribing and dispensing conduct that enables them to play a valuable role in the preventing diversion and fulfilling their obligations under the CSA.

745. The DEA, among others, has provided extensive guidance to National Pharmacies concerning their duties to the public. In particular, the guidance advises how to identify red flags and other evidence of diversion.

746. For example, DEA guidance instructs pharmacies to monitor for red flags that include: prescriptions written by a doctor who writes significantly more prescriptions (or in larger quantities or higher doses) for controlled substances compared to other practitioners in the area and prescriptions for antagonistic drugs, such as depressants and stimulants, at the same time. Most of the time, these attributes are not difficult to detect and should be easily recognizable by National Pharmacies' diversion control systems.

²⁵² See, e.g., Holiday CVS, L.L.C., d/b/a CVS/Pharmacy Nos. 219 and 5195; 77 Fed. Reg. 62,315 (Dep't of Justice Oct. 12, 2012) (decision and order); East Main Street Pharmacy, 75 Fed. Reg. 66,149 (Dep't of Justice Oct. 27, 2010) (affirmance of suspension order); Holiday CVS, L.L.C. v. Holder, 839 F.Supp.2d 145 (D.D.C. 2012); Townwood Pharmacy; 63 Fed. Reg. 8,477 (Dep't of Justice Feb. 19, 1998) (revocation of registration); Grider Drug 1 & Grider Drug 2; 77 Fed. Reg. 44,069 (Dep't of Justice July 26, 2012) (decision and order); The Medicine Dropper; 76 Fed. Reg. 20,039 (Dep't of Justice April 11, 2011) (revocation of registration); Medicine Shoppe-Jonesborough; 73 Fed. Reg. 363 (Dep't of Justice Jan. 2, 2008) (revocation of registration)

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

747. Other signs of diversion can be observed through data gathered, consolidated, and analyzed by the National Pharmacies. That data allows them to observe patterns or instances of dispensing that are potentially suspicious, of oversupply in particular stores or geographic areas, or of prescribers or facilities that seem to engage in improper prescribing.

748. In 2006, the National Association of Chain Drug Stores (“NACDS”) issued a “Model Compliance Manual” intended to “assist NACDS members” in developing their own compliance programs.²⁵³ The Model Compliance Manual notes that a Retail Pharmacy may:

Generate and review reports for its own purposes” and refers to the assessment tools identified by CMS in its Prescription Drug Benefit Manual chapter on fraud, waste and abuse, including:

- Drug Utilization Reports, which identify the number of prescriptions filled for a particular customer and, in particular, numbers for suspect classes of drugs such as narcotics to identify possible therapeutic abuse or illegal activity by a customer. A customer with an abnormal number of prescriptions or prescription patterns for certain drugs should be identified in reports, and the customer and his or her prescribing providers can be contacted and explanations for use can be received.
- Prescribing Patterns by Physician Reports, which identify the number of prescriptions written by a particular provider and focus on a class or particular type of drug such as narcotics. These reports can be generated to identify possible prescriber or other fraud.
- Geographic Zip Reports, which identify possible "doctor shopping" schemes or "script mills" by comparing the geographic location (zip code) of the patient to the location of the provider who wrote the prescription and should include the location of the dispensing pharmacy.

749. According to industry standards, if a pharmacy finds evidence of prescription diversion, the local Board of Pharmacy and DEA must be contacted.

²⁵³ CAH_MDL2804_00842870

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

4. Supply Chain Defendants and National Pharmacies Were Aware of and Have Acknowledged Their Obligations to Prevent Diversion and to Report and Take Steps to Halt Suspicious Orders

750. The reason for the reporting rules is to create a “closed” system intended to control the supply and reduce the diversion of these drugs out of legitimate channels into the illicit market, while at the same time providing the legitimate drug industry with a unified approach to narcotic and dangerous drug control.

751. Supply Chain Defendants and National Pharmacies were well aware they had an important role to play in this system, and also knew or should have known that their failure to comply with their obligations would have serious consequences.

752. Trade organizations to which the Supply Chain Defendants and National Pharmacies belong have acknowledged the importance of maintaining systems to prevent diversion, including, with respect to Supply Chain Defendants, systems to identify, halt, and report suspicious orders.²⁵⁴ The Healthcare Distribution Alliance (“HDA”)²⁵⁵ a trade association of pharmaceutical distributors that also includes affiliate manufacturer members, as well as the National Association of Chain Drug Stores (“NACDS”)²⁵⁶, have both long taken the position that these Defendants have responsibilities to “prevent diversion of controlled prescription drugs” not only because they have statutory and regulatory obligations do so, but “as responsible members of society.” Guidelines established by the HDA also explain that distributors, “[a]t the center of a

²⁵⁴ See Brief for Healthcare Distribution Management Association and National Association of Chain Drug Stores as Amici Curiae in Support of Neither Party, *Masters Pharmaceuticals, Inc. v. Drug Enforcement Administration*, 2012 WL 1321983, at *4 (D.C. Cir. Apr. 4, 2016) (stating that regulations “in place for more than 40 years require distributors to report suspicious orders of controlled substances to DEA . . .”) (emphasis omitted).

²⁵⁵ From 2001 to 2016, the HDA was known as the Healthcare Distribution Management Association (“HDMA”). Prior to 2001, HDMA was named the National Wholesale Druggists’ Association (“NWDA”).

²⁵⁶ NACDS is a trade organization whose members include “over 80 chain member companies,” including regional chains with a minimum of four stores and national companies. NACDS members also include more than 900 supplier partners. NACDS’s current Board includes Walgreens, CVS, Rite Aid, and Kroger. See National Association of Chain Drug Stores, “Leadership,” available at <https://www.nacds.org/>.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

sophisticated supply chain . . . are uniquely situated to perform due diligence in order to help support the security of the controlled substances they deliver to their customers.”

753. As discussed above, the DEA has also repeatedly reminded the Supply Chain Defendants of their obligations to report and decline to fill suspicious orders.

754. Supply Chain Defendants’ own documents further internally acknowledge their duties – and the impact of failing to comply with them. For example, a McKesson presentation, titled “State of Prescription Drug Abuse” and subtitled “Protecting America from Prescription Drug Abuse: The Impact of Effective Compliance” was authored by former DEA Agent Gary Boggs, who ultimately became the Senior Director of Regulatory Affairs at McKesson. The presentation acknowledges the “power” held by the DEA registrants, including the Supply Chain Defendants, but notes that with that “Great Power Comes Great Responsibility,” and the importance of “compliances” with the CSA “checks and balances” to impact and prevent diversion, stating that “Registrants are a force multiplier... [w]ithout sustained sources of supply major diversion schemes wither away.”²⁵⁷

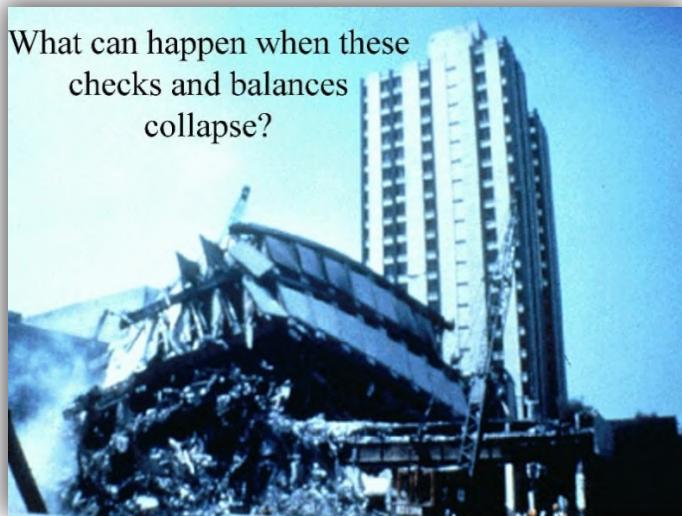
755. McKesson’s presentation describes the Controlled Substances Act’s “closed system of distribution” as creating a “system of checks and balances between registrants to protect the public health and safety.”²⁵⁸ McKesson’s presentation asserts that when the checks and balances collapse, the result is disaster for the public health and safety.²⁵⁹

²⁵⁷ MCMKMDL00336833

²⁵⁸ MCMKMDL00336833

²⁵⁹ MCMKMDL00336833

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER



756. McKesson's presentation further emphasizes the importance of not simply having a nominal system, but actually taking steps to prevent diversion:

Detecting Suspicious Orders

- Do not rely solely on thresholds or algorithms as a shortcut to detecting suspicious orders
- Most importantly, USE your system
 - Cannot ignore warning signs
 - Listen to employees when they do identify suspicious orders.

757. Supply Chain Defendants were well aware of their duty to be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

5. Defendants Kept Careful Track of Prescribing Data and Knew About Suspicious Orders and Prescribers

758. The data that reveals and/or confirms the identity of each wrongful opioid distributor is hidden from public view in the DEA's confidential ARCOS database. The data necessary to identify with specificity the transactions that were suspicious is in possession of the Supply Chain Defendants but has not been disclosed to the public.

759. Publicly available information confirms that Distributor and Manufacturer Defendants funneled far more opioids into communities across the United States than could have been expected to serve legitimate medical use and ignored red flags of diversion. This information, along with the information known only to the Supply Chain Defendants, would have alerted them to potentially suspicious orders of opioids.

760. This information includes the following facts:

- a. Distributors and manufacturers have access to detailed transaction-level data on the sale and distribution of opioids, which can be broken down by zip code, prescriber, and pharmacy and includes the volume of opioids, dose, and the distribution of other controlled and non-controlled substances;
- b. Manufacturers make use of that data to target their marketing and, for that purpose, regularly monitor the activity of doctors and pharmacies;
- c. Manufacturers and distributors regularly visit pharmacies and doctors to promote and provide their products and services, which allows them to observe red flags of diversion, as described in paragraphs 186 and 200;
- d. Distributor Defendants, together, account for approximately 90% of all revenues from prescription drug distribution in the United States, and each plays such a large part in the distribution of opioids that its own volume provides a ready vehicle for measuring the overall flow of opioids into a pharmacy or geographic area; and
- e. Manufacturer Defendants purchased chargeback data (in return for discounts to Distributor Defendants) that allowed them to monitor the combined flow of opioids into a pharmacy or geographic area.
- f. National Pharmacy Defendants developed and maintained extensive data on the opioids they distributed and dispensed. The National Pharmacies would provide

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

other Defendants with this data in exchange for rebates or other forms of consideration or would sell this data to companies such as IMS Health.

761. The conclusion that the Supply Chain Defendants and National Pharmacies were on notice of the problems of abuse and diversion follows inescapably from the fact that they flooded communities with opioids in quantities that they knew or should have known exceeded any legitimate market for opioids – even the wider market for chronic pain.

762. At all relevant times, the Supply Chain Defendants and National Pharmacies were in possession of national, regional, state, and local prescriber-and patient-level data that allowed them to track prescribing patterns over time. They obtained this information from data companies, including but not limited to: IMS Health, QuintilesIMS, IQVIA, Pharmaceutical Data Services, Source Healthcare Analytics, NDS Health Information Services, Verispan, Quintiles, SDI Health, ArcLight, Scriptline, Wolters Kluwer, and/or PRA Health Science, and all of their predecessors or successors in interest (the “Data Vendors”).

763. The Distributor Defendants developed “know your customer” questionnaires and files. This information, compiled pursuant to comments from the DEA in 2006 and 2007 was intended to help the Defendants identify suspicious orders or customers who were likely to divert prescription opioids.²⁶⁰ The “know your customer” questionnaires informed the Distributor Defendants of the number of pills that the pharmacies sold, how many non-controlled substances were sold compared to controlled substances, whether the pharmacy buys from other distributors, the types of medical providers in the area, including pain clinics, general practitioners, hospice

²⁶⁰ *Suggested Questions a Distributor Should Ask Prior to Shipping Controlled Substances*, Drug Enforcement Admin. Diversion Control Div., https://www.deadiversion.usdoj.gov/mtgs/pharm_industry/14th_pharm/levinl_ques.pdf; Richard Widup, Jr., Kathleen H. Dooley, Esq. *Pharmaceutical Production Diversion: Beyond the PDMA*, Purdue Pharma and McGuireWoods LLC (Oct. 2010), https://www.mcguirewoods.com/news-resources/publications/lifesciences/product_diversion_beyond_pdma.pdf.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

facilities, cancer treatment facilities, among others, and these questionnaires put the recipients on notice of suspicious orders.

764. Defendants purchased nationwide, regional, state, and local prescriber- and patient-level data from the Data Vendors that allowed them to track prescribing trends, identify suspicious orders, identify patients who were doctor shopping, identify pill mills, etc. The Data Vendors' information purchased by the Defendants allowed them to view, analyze, compute, and track their competitors' sales, and to compare and analyze market share information.²⁶¹

765. IMS Health, for example, provided Defendants with reports detailing prescriber behavior and the number of prescriptions written between competing products.²⁶²

766. Similarly, Wolters Kluwer, an entity that eventually owned data mining companies that were created by McKesson (Source) and Cardinal Health (ArcLight), provided the Defendants with charts analyzing the weekly prescribing patterns of multiple physicians, organized by territory, regarding competing drugs, and analyzed the market share of those drugs.²⁶³

767. This information allowed the Defendants to track and identify instances of overprescribing. In fact, one of the Data Vendors' experts testified that the Data Vendors' information could be used to track, identify, report and halt suspicious orders of controlled substances.²⁶⁴

²⁶¹ A Verispan representative testified that the Supply Chain Defendants use the prescribing information to "drive market share." *Sorrell v. IMS Health Inc.*, No. 10-779, 2011 WL 661712, *9-10 (Feb. 22, 2011).

²⁶² Paul Kallukaran & Jerry Kagan, *Data Mining at IMS HEALTH: How We Turned a Mountain of Data into a Few Information-Rich Molehills*, (accessed on February 15, 2018),

<http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.198.349&rep=rep1&type=pdf> , Figure 2 at p.3.

²⁶³ Joint Appendix in *Sorrell v. IMS Health Inc.*, No. 10-779, 2011 WL 705207, *467-471 (Feb. 22, 2011).

²⁶⁴ In *Sorrell*, expert Eugene "Mick" Kolassa testified, on behalf of the Data Vendor, that "a firm that sells narcotic analgesics was able to use prescriber-identifiable information to identify physicians that seemed to be prescribing an inordinately high number of prescriptions for their product." *Id*; see also Joint Appendix in *Sorrell v. IMS Health*, No. 10-779, 2011 WL 687134, at *204 (Feb. 22, 2011).

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

768. The National Pharmacies also maintained extensive data on the opioids they distributed and dispensed and sold such data to companies such as IMS Health. In describing the type of information IMS would purchase from National Pharmacies such as “a CVS or Rite Aid,” one IMS employee testified:

We collect prescription information that includes basically on each prescription that we receive the drug that was dispensed, the day that it was dispensed and the amount that's being given to a patient some information about the prescribers that like their name and as well as the locations of the pharmacy. So that's the basic information that we collect.²⁶⁵

769. The IMS employee further explained that, after purchasing this data, IMS Health would sell it to “pharmaceutical companies, biotechnology companies, financial institutions, wholesalers, retailers, in some case payers.”²⁶⁶

770. Relatedly, CVS Caremark’s Director of Managed Care Operations, Scott Tierney, testified that CVS’s data vendors included IMS Health, Verispan, and Walters Kluwers and that CVS used the vendors for “analysis and aggregation of data” and “some consulting services.” He also testified that CVS would provide the vendors with “prescriber level data, drug level data, plane level data, [and] de-identified patient data.”²⁶⁷

771. On information and belief, the National Pharmacies would often provide other Supply Chain Defendants with data they had collected regarding, *inter alia*, individual doctors in exchange for rebates or other forms of consideration.

772. Because of the data they gathered, consolidated, and analyzed, the National Retail Pharmacy Defendants had knowledge of patterns and instances of improper distribution,

²⁶⁵ Joint Appendix in *Sorrell v. IMS Health Inc.*, No. 10-779, 2011 WL 687134 (U.S.) *134 (Feb. 22, 2011).

²⁶⁶ *Id.*

²⁶⁷ *Id.* at *245-246.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

prescribing, and use of prescription opioids in communities throughout the County and in the City of Huntington in particular.

773. The Supply Chain Defendants and National Pharmacies were, therefore, collectively aware of the suspicious orders that flowed daily from their manufacturing and distribution facilities.

774. Supply Chain Defendants and National Pharmacies refused to identify, investigate and report suspicious orders to the DEA when they became aware of the same despite their actual knowledge of drug diversion rings. As described in detail below, Defendants refused to identify suspicious orders and diverted drugs despite the DEA issuing final decisions against the Distributor Defendants in 178 registrant actions between 2008 and 2012²⁶⁸ and 117 recommended decisions in registrant actions from The Office of Administrative Law Judges. These numbers include seventy-six (76) actions involving orders to show cause and forty-one (41) actions involving immediate suspension orders, all for failure to report suspicious orders.²⁶⁹

775. Sales representatives were also aware that the prescription opioids they were promoting were being diverted, often with lethal consequences. As a sales representative wrote on a public forum:

Actions have consequences – so some patient gets Rx'd the 80mg OxyContin when they probably could have done okay on the 20mg (but their doctor got “sold” on the 80mg) and their teen son/daughter/child’s teen friend finds the pill bottle and takes out a few 80’s... next they’re at a pill party with other teens and some kid picks out a green pill from the bowl... they go to sleep and don’t wake up (because they don’t understand respiratory depression) Stupid decision for a teen to make...yes... but do they really deserve to die?

²⁶⁸ Evaluation and Inspections Div., Office of the Inspector Gen., U.S. Dep’t of Justice, *The Drug Enforcement Administration’s Adjudication of Registrant Actions* 6 (2014), <https://oig.justice.gov/reports/2014/e1403.pdf>.

²⁶⁹ *Id.*

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

776. Moreover, Manufacturer Defendants' sales incentives rewarded sales representatives who happened to have pill mills within their territories, enticing those representatives to look the other way even when their in-person visits to such clinics should have raised numerous red flags. In one example, a pain clinic in South Carolina was diverting massive quantities of OxyContin. People traveled to the clinic from towns as far as 100 miles away to get prescriptions, the DEA's diversion unit raided the clinic, and prosecutors eventually filed criminal charges against the doctors. But Purdue's sales representative for that territory, Eric Wilson, continued to promote OxyContin sales at the clinic. He reportedly told another local physician that this clinic accounted for 40% of the OxyContin sales in his territory. At that time, Wilson was Purdue's top-ranked sales representative. In response to news stories about this clinic, Purdue issued a statement, declaring that "if a doctor is intent on prescribing our medication inappropriately, such activity would continue regardless of whether we contacted the doctor or not."

777. In another example, a Purdue sales manager informed her supervisors in 2009 about a suspected pill mill in Los Angeles, reporting over email that when she visited the clinic with her sales representative, "it was packed with a line out the door, with people who looked like gang members," and that she felt "very certain that this an organized drug ring[.]" She wrote, "This is clearly diversion. Shouldn't the DEA be contacted about this?" But her supervisor at Purdue responded that while they were "considering all angles," it was "really up to [the wholesaler] to make the report." This pill mill was the source of 1.1 million pills trafficked to Everett, Washington, a city of around 100,000 people. Purdue waited until after the clinic was shut down in 2010 to inform the authorities.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

778. Defendants' obligation to report suspicious prescribing ran head on into their marketing strategy. Defendants did identify doctors who were their most prolific prescribers, but not to report them, but to market to them. It would make little sense to focus on marketing to doctors who may be engaged in improper prescribing only to report them to law enforcement, nor to report those doctors who drove Defendants' sales.

779. Defendants purchased data from IMS Health (now IQVIA) or other proprietary sources to identify doctors to target for marketing and to monitor their own and competitors' sales. Marketing visits were focused on increasing, sustaining, or converting the prescriptions of the biggest prescribers, particularly through aggressive, high frequency detailing visits.

780. For example, at a national sales meeting presentation in 2011, Actavis pressed its sales representatives to focus on its high prescribers: "To meet and exceed our quota, we must continue to get Kadian scripts from our loyalists. MCOs will continue to manage the pain products more closely. We MUST have new patient starts or we will fall back into 'the big leak'. We need to fill the bucket faster than it leaks." "The selling message should reflect the opportunity and prescribing preferences of each account. High Kadian Writers / Protect and Grow/ Grow = New Patient Starts and Conversions." In an example of how new patients + a high volume physician can impact performance: "102% of quota was achieved by just one high volume physician initiating Kadian on 2-3 new patients per week."²⁷⁰

781. The same is true for other Defendants.²⁷¹ Teva directed its sales representatives to make a "minimum of seven Fentora calls per day" and focus "on high prescribers to maintain and grow their contribution." Another chart showed Cephalon ensured that the majority highest-volume or "core prescribers," were detailed at least five times in ten months.

²⁷⁰ ACTAVIS0969604, at 616.

²⁷¹ TEVA_CH_00002233.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

782. This focus on marketing to the highest prescribers had two impacts. First, it demonstrates that manufacturers were keenly aware of the doctors who were writing large quantities of opioids. Second, it demonstrated that instead of investigating or reporting those doctors, Defendants were singularly focused on maintaining, capturing, or increasing their sales.

783. Whenever examples of opioid diversion and abuse have drawn media attention, Manufacturer Defendants have consistently blamed “bad actors.” For example, in 2001, during a Congressional hearing, Purdue’s attorney Howard Udell answered pointed questions about how it was that Purdue could utilize IMS Health data to assess their marketing efforts but not notice a particularly egregious pill mill in Pennsylvania run by a doctor named Richard Paolino. Udell asserted that Purdue was “fooled” by the doctor: “The picture that is painted in the newspaper [of Dr. Paolino] is of a horrible, bad actor, someone who preyed upon this community, who caused untold suffering. And he fooled us all. He fooled law enforcement. He fooled the DEA. He fooled local law enforcement. He fooled us.”

784. But given the closeness with which Defendants monitored prescribing patterns through IMS Health data, it is highly improbable that they were “fooled.” In fact, a local pharmacist had noticed the volume of prescriptions coming from Paolino’s clinic and alerted authorities. Purdue had the prescribing data from the clinic and alerted no one. Indeed, a Purdue executive referred to Purdue’s tracking system and database as a “gold mine” and acknowledged that Purdue could identify highly suspicious volumes of prescriptions.

785. As discussed below, Endo knew that Opana ER was being widely abused. Yet, the New York Attorney General revealed, based on information obtained in an investigation into Endo, that Endo sales representatives were not aware that they had a duty to report suspicious activity and were not trained on the company’s policies or duties to report suspicious activity, and Endo

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

paid bonuses to sales representatives for detailing prescribers who were subsequently arrested for illegal prescribing.

786. Sales representatives making in-person visits to such clinics were likewise not fooled. But as pill mills were lucrative for the manufacturers and individual sales representatives alike, Manufacturer Defendants and their employees turned a collective blind eye, allowing certain clinics to dispense staggering quantities of potent opioids and feigning surprise when the most egregious examples eventually made the nightly news.

6. Despite Repeated Admonitions, Supply Chain Defendants Continued to Violate their Legal Obligations and Failed to Act to Prevent Diversion.

787. A number of Defendants have faced repeated enforcement actions for their failure to comply with their obligations to report and decline suspicious orders, making clear both that they were repeatedly reminded of their duties, and that they frequently failed to meet them.

788. In May 2014, the United States Department of Justice, Office of the Inspector General, Evaluation and Inspections Divisions, reported that the DEA issued final decisions in 178 registrant actions between 2008 and 2012. These included, among others:

- a. On April 24, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the AmerisourceBergen Orlando, Florida distribution center (“Orlando Facility”) alleging failure to maintain effective controls against diversion of controlled substances. On June 22, 2007, AmerisourceBergen entered into a settlement that resulted in the suspension of its DEA registration;
- b. On November 28, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Auburn, Washington Distribution Center (“Auburn Facility”) for failure to maintain effective controls against diversion of hydrocodone;
- c. On December 5, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Lakeland, Florida Distribution Center (“Lakeland Facility”) for failure to maintain effective controls against diversion of hydrocodone;

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

d. On December 7, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Swedesboro, New Jersey Distribution Center (“Swedesboro Facility”) for failure to maintain effective controls against diversion of hydrocodone;

e. On January 30, 2008, the DEA issued an *Order to Show Cause* against the Cardinal Health Stafford, Texas Distribution Center (“Stafford Facility”) for failure to maintain effective controls against diversion of hydrocodone;

f. On May 2, 2008, McKesson Corporation entered into an *Administrative Memorandum of Agreement* (“2008 McKesson MOA”) with the DEA which provided that McKesson would “maintain a compliance program designed to detect and prevent the diversion of controlled substances, inform DEA of suspicious orders required by 21 C.F.R. § 1301.74(b), and follow the procedures established by its Controlled Substance Monitoring Program”;

g. On September 30, 2008, Cardinal Health entered into a *Settlement and Release Agreement and Administrative Memorandum of Agreement* with the DEA related to its Auburn, Lakeland, Swedesboro and Stafford Facilities. The document also referenced allegations by the DEA that Cardinal failed to maintain effective controls against the diversion of controlled substances at its distribution facilities located in McDonough, Georgia (“McDonough Facility”), Valencia, California (“Valencia Facility”) and Denver, Colorado (“Denver Facility”);

h. On February 2, 2012, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health’s Lakeland Facility for failure to maintain effective controls against diversion of oxycodone; and

i. On December 23, 2016, Cardinal Health agreed to pay a \$44 million fine to the DEA to resolve the civil penalty portion of the administrative action taken against its Lakeland, Florida Distribution Center.

789. Pursuant to an Administrative Memorandum of Agreement (“2017 Agreement”) entered into between Defendant McKesson and the DEA in January 2017, McKesson admitted that it breached its duties to monitor, report, and prevent suspicious orders and that, at various times during the period from January 1, 2009 through the effective date of the Agreement (January 17, 2017), it “did not identify or report to [the] DEA certain orders placed by certain pharmacies which should have been detected by McKesson as suspicious based on the guidance contained in

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

the DEA Letters.”²⁷² Further, the 2017 Agreement specifically finds that McKesson “distributed controlled substances to pharmacies even though those McKesson Distribution Centers should have known that the pharmacists practicing within those pharmacies had failed to fulfill their corresponding responsibility to ensure that controlled substances were dispensed pursuant to prescriptions issued for legitimate medical purposes by practitioners acting in the usual course of their professional practice, as required by 21 C.F.R § 1306.04(a).”²⁷³ McKesson admitted that, during this time period, it “failed to maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific and industrial channels by sales to certain of its customers in violation of the CSA and the CSA’s implementing regulations, 21 C.F.R. Part 1300 et seq., at the McKesson Distribution Centers.”

790. As the *Washington Post* and *60 Minutes* recently reported, DEA staff recommended a much larger penalty, as much as a billion dollars, and delicensing of certain facilities.²⁷⁴ A DEA memo outlining the investigative findings in connection with the administrative case against 12 McKesson distribution centers included in the 2017 Settlement stated that McKesson “[s]upplied controlled substances in support of criminal diversion activities”; “[i]gnored blatant diversion”; had a “[p]attern of raising thresholds arbitrarily”; “[f]ailed to review orders or suspicious activity”; and “[i]gnored [the company’s] own procedures designed to prevent diversion.”²⁷⁵ Investigators found certain warehouses “were supplying pharmacies that sold to criminal drug rings.”²⁷⁶

²⁷² Settlement Agreement and Release between the U.S. and McKesson Corp., at 5 (Jan. 17, 2017) [hereinafter “2017 Settlement Agreement and Release”] (“McKesson acknowledges that, at various times during the Covered Time Period [2009-2017], it did not identify or report to DEA certain orders placed by certain pharmacies, which should have been detected by McKesson as suspicious, in a manner fully consistent with the requirements set forth in the 2008 MOA.”), available at <https://www.justice.gov/opa/press-release/file/928471/download>.

²⁷³ *Id.*

²⁷⁴ Lenny Bernstein and Scott Higham, “‘We Feel Like Our System Was Hijacked’: DEA Agents Say a Huge Opioid Case Ended in a Whimper, Washington Post (Dec. 17, 2017).

²⁷⁵ Lenny Bernstein and Scott Higham, “‘We Feel Like Our System Was Hijacked’: DEA Agents Say a Huge Opioid Case Ended in a Whimper, Washington Post (Dec. 17, 2017).

²⁷⁶ *Id.*

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

791. Even the far lesser-than recommended civil penalty against McKesson, a \$150 million fine, was record breaking. In addition to the monetary penalty, the DOJ required McKesson to suspend sales of controlled substances from distribution centers in four different states. Though this penalty too, was far less severe than investigators had recommended, as the DOJ explained, these “staged suspensions” are nevertheless “among the most severe sanctions ever agreed to by a [Drug Enforcement Administration] registered distributor.”²⁷⁷

792. In short, McKesson, was “neither rehabilitated nor deterred by the 2008 [agreement],” as a DEA official working on the case noted.²⁷⁸ Quite the opposite, “‘their bad acts continued and escalated to a level of egregiousness not seen before.’”²⁷⁹ According to statements of “DEA investigators, agents and supervisors who worked on the McKesson case” reported in the *Washington Post*, “the company paid little or no attention to the unusually large and frequent orders placed by pharmacies, some of them knowingly supplying the drug rings.”²⁸⁰ “Instead, the DEA officials said, the company raised its own self-imposed limits, known as thresholds, on orders from pharmacies and continued to ship increasing amounts of drugs in the face of numerous red flags.”²⁸¹

793. Further, in a *60 Minutes* interview last fall, former DEA agent Joe Rannazzisi described Distributor Defendants’ industry as “out of control,” stating that “[w]hat they wanna do,

²⁷⁷ Department of Justice, “McKesson Agrees to Pay Record \$150 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs, (Jan. 17, 2017) <https://www.justice.gov/opa/pr/mckesson-agrees-pay-record-150-million-settlement-failure-report-suspicious-orders>.

²⁷⁸ Lenny Bernstein and Scott Higham, “‘We Feel Like Our System Was Hijacked’: DEA Agents Say a Huge Opioid Case Ended in a Whimper, Washington Post (Dec. 17, 2017), https://www.washingtonpost.com/investigations/mckesson-dea-opioids-fine/2017/12/14/ab50ad0e-db5b-11e7-b1a8-62589434a581_story.html?utm_term=.d6e92f349f47

²⁷⁹ *Id.* (quoting a March 30, 2015 DEA memo).

²⁸⁰ *Id.*

²⁸¹ *Id.*

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

is do what they wanna do, and not worry about what the law is. And if they don't follow the law in drug supply, people die. That's just it. People die.”²⁸² He further explained that:

JOE RANNAZZISI: The three largest distributors are Cardinal Health, McKesson, and AmerisourceBergen. They control probably 85 or 90 percent of the drugs going downstream.

[INTERVIEWER]: You know the implication of what you're saying, that these big companies knew that they were pumping drugs into American communities that were killing people.

JOE RANNAZZISI: That's not an implication, that's a fact. That's exactly what they did.²⁸³

794. Another DEA veteran similarly stated that these companies failed to make even a “good faith effort” to “do the right thing.”²⁸⁴ He further explained that “I can tell you with 100 percent accuracy that we were in there on multiple occasions trying to get them to change their behavior. And they just flat out ignored us.”²⁸⁵

795. The Distributor Defendants were not alone in failing to live up to their reporting obligations. As discussed above, Mallinckrodt recently paid a \$35 million for failure to report suspicious orders of controlled substances, including opioids, and for violating recordkeeping requirements.²⁸⁶ In addition, Mallinckrodt admitted in a settlement with DEA that “[a]s a registrant under the CSA, Mallinckrodt had a responsibility to maintain effective controls against

²⁸² Bill Whitaker, *Ex-DEA Agent : Opioid Crisis Fueled by Drug Industry and Congress*, CBS News (Oct. 17, 2017), <https://www.cbsnews.com/news/ex-dea-agent-opioid-crisis-fueled-by-drug-industry-and-Congress>

²⁸³ *Id.*

²⁸⁴ *Id.*

²⁸⁵ *Id.*

²⁸⁶ See Press Release, U.S. Dep’t of Justice, Mallinckrodt Agrees to Pay Record \$35 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs and for Recordkeeping Violations (July 11, 2017), <https://www.justice.gov/opa/pr/mallinckrodt-agrees-pay-record-35-million-settlement-failure-report-suspicious-orders>.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

diversion, including a requirement that it review and monitor these sales and report suspicious orders to DEA.”²⁸⁷

796. In the press release accompanying the settlement, the Department of Justice stated: “Mallinckrodt did not meet its obligations to detect and notify DEA of suspicious orders of controlled substances such as oxycodone, the abuse of which is part of the current opioid epidemic. These suspicious order monitoring requirements exist to prevent excessive sales of controlled substances, like oxycodone Mallinckrodt’s actions and omissions formed a link in the chain of supply that resulted in millions of oxycodone pills being sold on the street. . . . Manufacturers and distributors have a crucial responsibility to ensure that controlled substances do not get into the wrong hands. . . .”²⁸⁸

797. Among the allegations resolved by the settlement, the government alleged “Mallinckrodt failed to design and implement an effective system to detect and report ‘suspicious orders’ for controlled substances—orders that are unusual in their frequency, size, or other patterns . . . [and] Mallinckrodt supplied distributors, and the distributors then supplied various U.S. pharmacies and pain clinics, an increasingly excessive quantity of oxycodone pills without notifying DEA of these suspicious orders.”²⁸⁹

798. The 2017 Mallinckrodt MOA further details the DEA’s allegations regarding Mallinckrodt’s failures to fulfill its legal duties as an opioid manufacturer:

With respect to its distribution of oxycodone and hydrocodone products, Mallinckrodt’s alleged failure to distribute these controlled substances in a manner authorized by its registration and Mallinckrodt’s alleged failure to operate an effective suspicious

²⁸⁷ 2017 Mallinckrodt MOA.

²⁸⁸ See Press Release, U.S. Dep’t of Justice, Mallinckrodt Agrees to Pay Record \$35 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs and for Recordkeeping Violations (July 11, 2017), <https://www.justice.gov/opa/pr/mallinckrodt-agrees-pay-record-35-million-settlement-failure-report-suspicious-orders>.

²⁸⁹ *Id.*

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

order monitoring system and to report suspicious orders to the DEA when discovered as required by and in violation of 21 C.F.R. § 1301.74(b). The above includes, but is not limited to Mallinckrodt's alleged failure to:

- i. conduct adequate due diligence of its customers;
- ii. detect and report to the DEA orders of unusual size and frequency;
- iii. detect and report to the DEA orders deviating substantially from normal patterns including, but not limited to, those identified in letters from the DEA Deputy Assistant Administrator, Office of Diversion Control, to registrants dated September 27, 2006 and December 27, 2007:
 - 1.orders that resulted in a disproportionate amount of a substance which is most often abused going to a particular geographic region where there was known diversion,
 - 2.orders that purchased a disproportionate amount of a substance which is most often abused compared to other products, and
 - 3.orders from downstream customers to distributors who were purchasing from multiple different distributors, of which Mallinckrodt was aware;
- iv. use "chargeback" information from its distributors to evaluate suspicious orders. Chargebacks include downstream purchasing information tied to certain discounts, providing Mallinckrodt with data on buying patterns for Mallinckrodt products; and
- v. take sufficient action to prevent recurrence of diversion by downstream customers after receiving concrete information of diversion of Mallinckrodt product by those downstream customers.²⁹⁰

799. Mallinckrodt acknowledged that at certain times prior to January 1, 2012, "certain aspects of Mallinckrodt's system to monitor and detect suspicious orders did not meet the

²⁹⁰ 2017 Mallinckrodt MOA at 2-3.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

standards outlined in letter from the DEA Deputy Administrator, Office of Diversion Control, to registrants dated September 27, 2006 and December 27, 2007.”²⁹¹

800. Mallinckrodt also agreed that, from its chargeback data, it would “report to the DEA when Mallinckrodt concludes that the chargeback data or other information indicates that a downstream registrant poses a risk of diversion.”²⁹²

7. Supply Chain Defendants and National Pharmacies Breached Their Legal Duties and Failed to Prevent Diversion

801. Supply Chain Defendants and National Pharmacies failed to prevent diversion, or otherwise control the supply of opioids following into communities across the United States, including in Cabell County and the City of Huntington. Supply Chain Defendants further failed to report and halt shipment of suspicious orders. Despite the notice described above, and in disregard of their duties, Supply Chain Defendants and National Pharmacies continued to pump massive quantities of opioids despite their obligations to control the supply, prevent diversion, report and take steps to halt suspicious orders. Governmental agencies and regulators have confirmed (and in some cases these Defendants have admitted) that Supply Chain Defendants and National Pharmacies did not meet their obligations and have uncovered especially blatant wrongdoing.

802. Supply Chain Defendants and National Pharmacies failed to maintain effective control against diversion of prescriptions into the illicit market and Supply Chain Defendants failed to “design and operate a system to disclose . . . suspicious orders of controlled substances,” including “orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.” Because National Pharmacies were also distributors, they were complicit in the failures to report and halt suspicious orders.

²⁹¹ *Id.* at 3-4.

²⁹² 2017 Mallinckrodt MOA at 5.

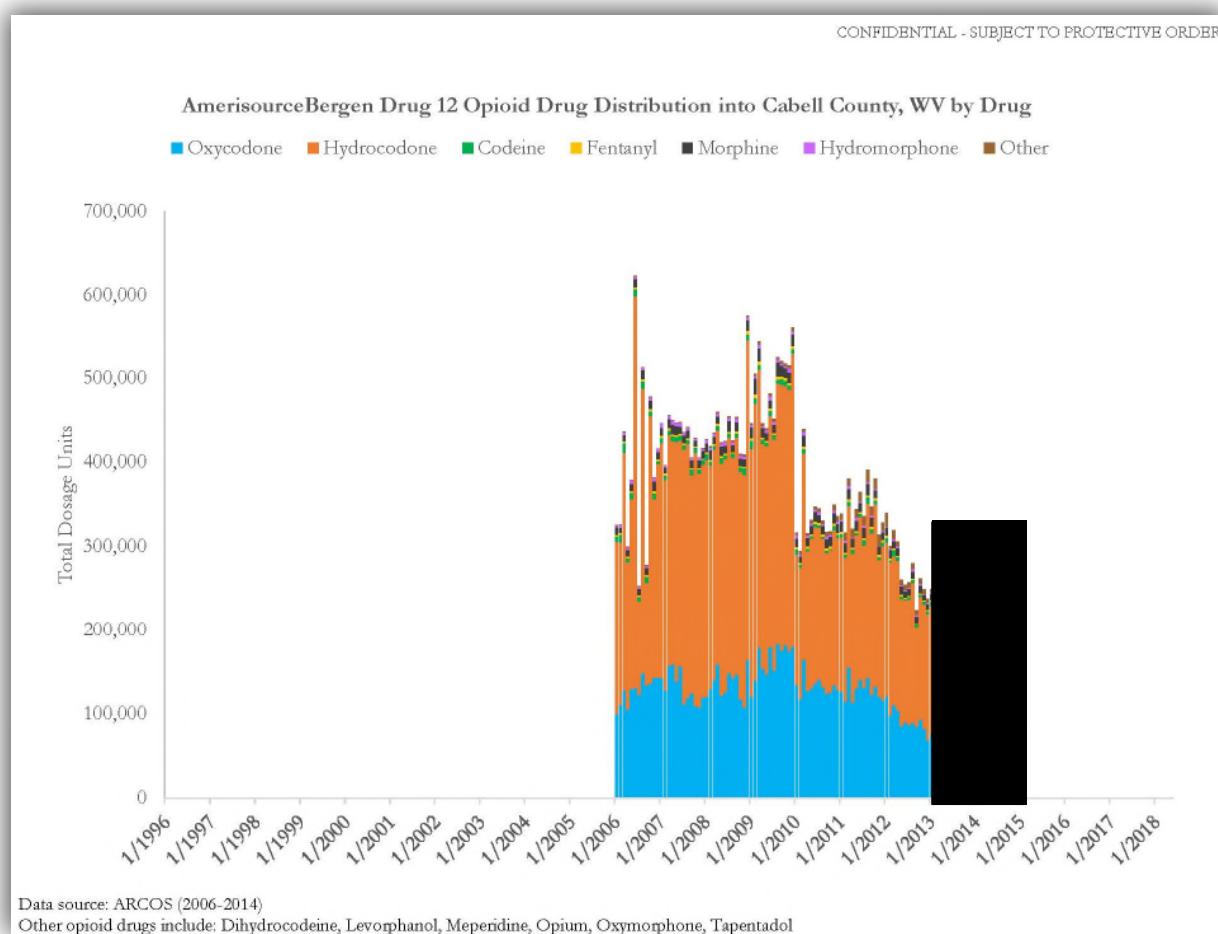
CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

803. Supply Chain Defendants and National Pharmacies breached their above stated duties under federal and state law by failing to: (a) control the supply chain; (b) prevent diversion; (c) report suspicious orders; (d) halt shipments of opioids in quantities they knew or should have known could not be justified and were indicative of serious problems of overuse of opioids; and/or (e) perform due diligence on orders which Supply Chain Defendants had reason to believe were suspicious, and instead shipping those orders without review.

i. AMERISOURCE BERGEN

804. Defendant AmerisourceBergen breached its duties under federal and state law.

805. As shown by the ARCOS Data, AmerisourceBergen distributed an extraordinary amount of prescription opioids into Plaintiffs' Community. AmerisourceBergen's excessive distribution was made possible by, and is evidence of, AmerisourceBergen's failures to comply with its duties under state and federal law, including the CSA.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

806. AmerisourceBergen failed to meet its suspicious order monitoring requirements, failed to stop shipment on suspicious orders, and failed to effectively prevent diversion in breach of its duties under state and federal law. These breaches contributed substantially to the public nuisance and harms alleged in the Plaintiffs' Community.

807. AmerisourceBergen's failures to effectively prevent diversion and stop shipment on suspicious orders are typified by its distribution to Safescript Pharmacy #6 ([REDACTED]).

808. From 2006-2012, AmerisourceBergen was the primary supplier of hydrocodone and oxycodone to SafeScript Pharmacy #6.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

809. From 2006-2012, Safescript Pharmacy #6 received more than 4.4 million dosage units of oxycodone and hydrocodone.²⁹³

810. In February 2012, the DOJ executed a search and seizure warrant on Safescript Pharmacy #6 and raided the pharmacy, which was owned and operated by one Wendall Kent Freeman, who is not a licensed pharmacist. Mr. Freeman was found with a drug ledger and multiple empty and improperly labeled prescription bottles and was arrested on drug charges. More than 180,000 doses of hydrocodone distributed to the pharmacy were unaccounted for.

811. AmerisourceBergen's breaches of its duties have persisted for many years, dating back to before 2007, when the DEA shut down one of AmerisourceBergen's distribution centers as part of an enforcement action. As of 2007, AmerisourceBergen's suspicious order monitoring system wholly failed the security requirement set forth in 21 C.F.R. § 1301.74(b). Specifically, AmerisourceBergen's pre-2007 policies constituted a failure to design and operate a system to identify suspicious orders because they only identified "excessive" orders that exceeded a three times threshold, which only took into consideration prior orders of that specific pharmacy. AmerisourceBergen's system did not take into consideration other relevant factors such as order frequency patterns, order averages of similar pharmacies, or comparisons of sales of Schedule II or III controlled substances with the sales of other controlled substances. AmerisourceBergen's also specifically failed to identify suspicious orders from internet pharmacies that the DEA concluded should have been identified.

812. AmerisourceBergen further violated the Reporting Requirement, violated the No-Shipping Requirement, and failed to perform meaningful due diligence. Pre-2007, while certain orders that exceeded the three times threshold were reported to the DEA, they were only reported

²⁹³ See ARCOS Data.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

after being shipped. AmerisourceBergen had no meaningful due diligence process in place to investigate whether “excessive” orders otherwise qualified as suspicious, other than an effort to make sure a customer was licensed with the state and registered with the DEA. AmerisourceBergen’s official national policy from 1990 up until the DEA Settlement 2007, was to ship *all* orders of controlled substances, regardless of size, frequency, deviations from prior orders, deviations from averages, deviations from defined thresholds, or whether that order was determined to be suspicious.

813. The 2007 enforcement action by the DEA was based on AmerisourceBergen filling and shipping orders from pharmacies, which according to the DEA, AmerisourceBergen knew to be suspicious.²⁹⁴ The enforcement action shut down AmerisourceBergen’s Orlando distribution center. On June 22, 2007, AmerisourceBergen and the DEA reached a settlement agreement in which AmerisourceBergen acknowledged it had “failed to maintain effective controls at the Orlando Facility against diversion of particular controlled substances into other than legitimate medical, scientific and industrial channels by sales to certain customers of AmerisourceBergen.”²⁹⁵ According to the April 19, 2007 Order to Show Cause and Immediate Suspension of Registration issued by the DEA, AmerisourceBergen distributed hydrocodone to pharmacies in amounts that far exceeded what an average pharmacy orders to meet the legitimate needs of its customers, distributed hydrocodone to pharmacies even though they ordered small amounts of other drug products relative to those purchases, distributed hydrocodone to pharmacies much more frequently than AmerisourceBergen’s other customers, and shipping to pharmacies that AmerisourceBergen knew or should have known many prescriptions were issued by physicians who did not conduct a

²⁹⁴ See ABDCMDL00269383-84.

²⁹⁵ See ABDCMDL00279854.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

medical examination of its customers, and instead wrote prescriptions for controlled substances ordered by customers over the internet.²⁹⁶

814. The failures the DEA found in AmerisourceBergen’s suspicious order monitoring program were systemic because AmerisourceBergen maintained national suspicious order monitoring policies and procedures.²⁹⁷

815. In order to obtain authorization from the DEA to re-open the Orlando facility, AmerisourceBergen was required to update its diversion control program, including adding (1) a more in-depth due diligence process; and (2) a requirement to stop shipping suspicious orders to customers.²⁹⁸ However, despite these requirements, AmerisourceBergen still failed to comply with its obligations under the CSA.

816. Post-2007, AmerisourceBergen still failed to design and operate an adequate system to identify suspicious orders because it continued to employ a “threshold-based system,” which was based on an arbitrary three times multiplier among drug families and, which continued to ignore other relevant information. AmerisourceBergen also left critical discretion to identify suspicious orders with its distribution center employees, without putting in place any concrete rules or criteria on how suspicious orders should be identified. Accordingly, AmerisourceBergen failed to identify and grossly underreported suspicious orders.

817. Further, while AmerisourceBergen purported to change its system in 2007 pursuant to its settlement agreement with the DEA, it still did not fully comply with the No-Shipping Requirement after that date. In certain cases, even orders reported to the DEA were shipped anyway, rather than being held or cancelled.

²⁹⁶ See ABDCMDL00269383-387.

²⁹⁷ See Mays Deposition II, 24:18-22.

²⁹⁸ See Zimmerman Deposition, 139:20-140:8; see also Settlement and Release Agreement, ABDCMDL00279854–00279865.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

818. An Audit Report performed of AmerisourceBergen’s SOM system in 2015 cited numerous problems with AmerisourceBergen’s SOM system, including a lack of resources, a lack of formal training, overburdened workloads, crushing administrative demands, inconsistent policies, and communications break-downs, which contributed to “gaps and risks” in AmerisourceBergen’s ability to identify orders as suspicious and prevent diversion.

819. AmerisourceBergen’s efforts of due diligence in identifying suspicious orders at this time also fell well short of effective. Specifically, AmerisourceBergen’s “Know Your Customer” due diligence policy was based on a form filled out by AmerisourceBergen’s own sales representatives in conjunction with AmerisourceBergen’s pharmacy customers, creating a conflict of interest in identifying accurate information. As AmerisourceBergen acknowledged internally regarding its targeted pharmacy visits, its true goal “is always to maintain the entity as an ABC customer.”²⁹⁹ Additionally, AmerisourceBergen’s chain retail pharmacy customers were exempt from the requirement to provide certain KYC information, which improperly abdicated AmerisourceBergen’s duty to identify suspicious orders to the customers themselves. Further, AmerisourceBergen’s due diligence program itself was inconsistently implemented, leaving a lack of current and historical documentation of due diligence efforts that renders a robust, effective due diligence system impossible. Internally, AmerisourceBergen admitted to having only “about 10% of the required customer due diligence documents,” acknowledging that such a failure put AmerisourceBergen “at risk with regulators.”³⁰⁰

820. Rather than focusing on putting effective controls to prevent diversion in place and designing and operating a system to detect suspicious orders and stopping those orders, AmerisourceBergen circumvented the requirements and coached customers on how to avoid being

²⁹⁹ BDCMDL00364844

³⁰⁰ ABDCMDL00159415

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

detected by the system and being the subject of an enforcement action by the DEA. For example, a July 2013 AmerisourceBergen document entitled “Sales Talking Points” warned an AmerisourceBergen customer that its “overall volume” and “percentage of C2 orders is high and may be deemed suspicious by either our OMP system or regulatory authorities. *This puts your account with ABDC at significant risk of closure or exposure to regulatory and enforcement agencies actions.* Every day, we read about another independent pharmacy under investigation. *I want to make sure that doesn’t happen to you.*” AmerisourceBergen then counseled the customer not to order fewer controlled substances, but to strategically format their ordering patterns so that they would not get flagged by SOMs programs or regulators.³⁰¹

821. AmerisourceBergen well knew the consequence of failing to meet its obligations under the CSA. AmerisourceBergen’s chief compliance officer admitted that if AmerisourceBergen did not adhere to “our effective controls to prevent diversion, yes, diversion could occur.”³⁰² As discussed above, however, the evidence shows that AmerisourceBergen consistently ignored critical red flags and warning signs from its customers in what amounts to a structural break-down of its diversion prevention obligations under the CSA, which had real consequences in the communities where AmerisourceBergen shipped dangerous drugs, like prescription opioids.

ii. CARDINAL HEALTH

822. Defendant Cardinal Health breached its duties under federal and state law.

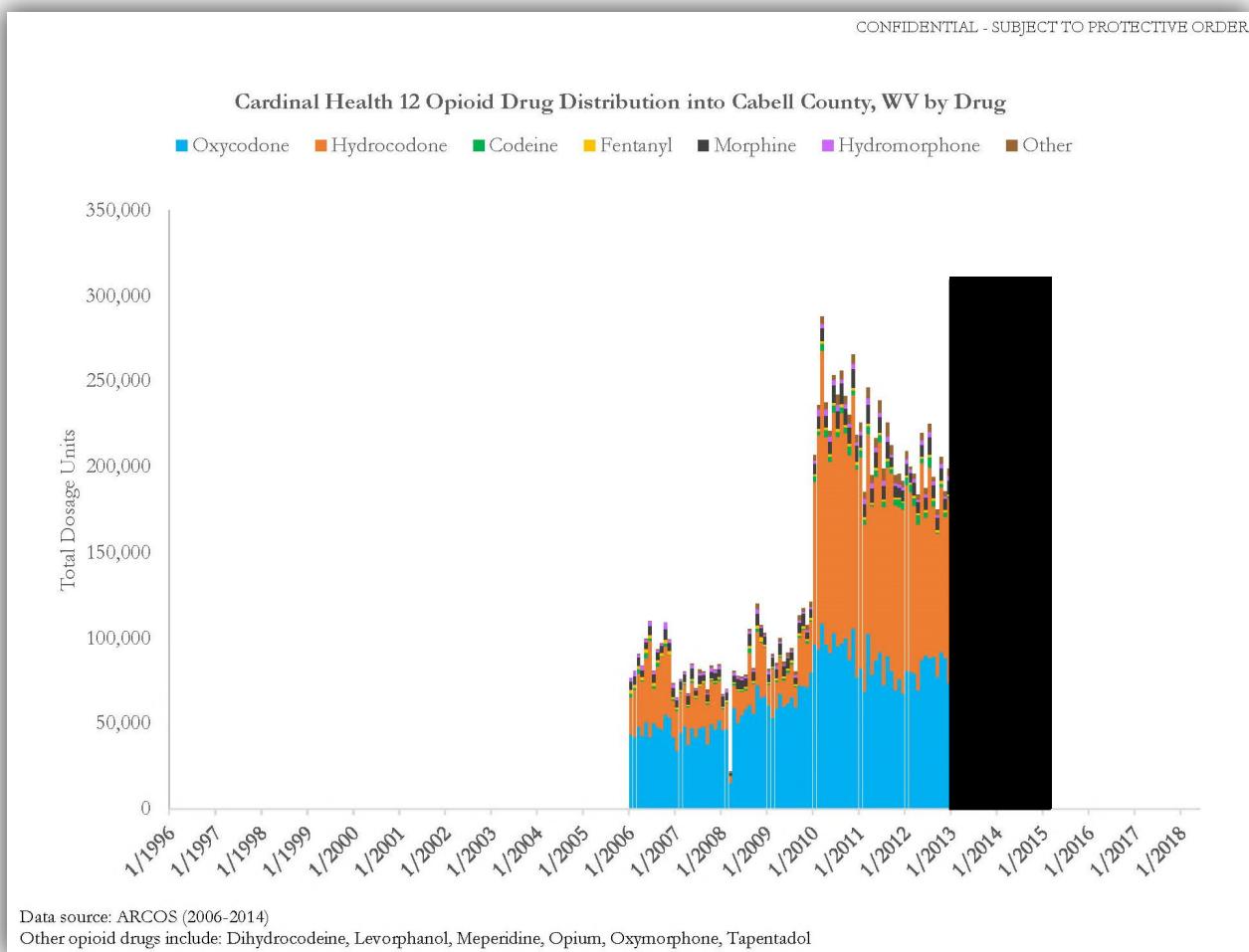
823. As shown by the ARCos Data, Cardinal Health distributed an extraordinary amount of prescription opioids into Plaintiffs’ Community. Cardinal Health’s excessive

³⁰¹ ABDCMDL00278212 (emphasis added).

³⁰² See Zimmerman Deposition, 104:14-17.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

distribution was made possible by, and is evidence of, Cardinal Health's failures to comply with its duties under state and federal law, including the CSA.



824. Cardinal Health failed to meet its suspicious order monitoring requirements, failed to stop shipment on suspicious orders, and failed to effectively prevent diversion in breach of its duties under state and federal law. These breaches contributed substantially to the public nuisance and harms alleged in the Plaintiffs' Community.

825. Cardinal Health's greed caused it to ignore its obligations to protect against diversion, distributing billions of opioid pills without anything resembling an adequate suspicious order monitoring system until at least 2008. To the extent Cardinal's suspicious order monitoring

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

program has improved, it has done so only as a result of the investigations and fines levied by the DEA and state attorneys general, in spite of having nearly unlimited resources and knowledge at its fingertips.

826. Cardinal's attempts at compliance with the Controlled Substances Act is historically reactionary; modifications and changes to Cardinal's suspicious order monitoring and reporting systems over the last two decades came only as a result of the governmental investigations, fines levied by the DEA and state attorneys general, and Congressional Hearings. Despite being one of the largest corporations in the United States, Cardinal failed to implement a system that would comply with the Controlled Substances Act.

827. As a DEA registrant and wholesale distributor, Cardinal Health was required by Congress to maintain effective control against diversion of prescription opiates and required by the DEA to identify, block and report suspicious orders from pharmacies. Cardinal Health blatantly failed in each regard resulting in the widespread diversion of prescription opioids.

828. From 2006 through 2014, Cardinal Health distributed [REDACTED] dosage units of opioids into Cabell County, West Virginia alone. Of these, oxycodone and hydrocodone accounted for more than [REDACTED] pills and more than doubled from 2006 to 2010, remaining at escalated number through at least 2014, when Cardinal distributed more than [REDACTED] dosage units of oxycodone and hydrocodone alone into Cabell County.³⁰³

829. From 1996 to 2008, Cardinal Health did not have an anti-diversion program that could adequately monitor and detect suspicious orders of opioids or timely report any suspicious orders.

³⁰³ See ARCOS Data produced in MDL 2804.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

830. Cardinal Health adopted a DEA Compliance Manual³⁰⁴ as early as April 4, 2000, which contained a corporate policy on suspicious order reporting.³⁰⁵ The policy provided for after-the-fact reporting and a cage vault rule placing a cap on individual sales. The policy was in effect at least through June 15, 2006.³⁰⁶

831. According to its policies and procedures, Cardinal identified suspicious orders prior to shipment via each distribution center’s “pickers and checkers” - distribution center cage/vault personnel responsible for physically “picking” customers’ orders from warehouse shelves for packaging and “checking” the contents of the package to ensure the order was filled correctly. According to Cardinal’s DEA Compliance Manual, the “pickers and checkers” were responsible for policing individual orders that appeared excessive in relation to other customers’ ordering patterns or that customer’s order history. Cardinal developed and posted in the distribution centers’ cage/vault areas an “Excessive Purchases Schedule” for pickers and checkers to use to identify suspicious orders.³⁰⁷

832. Cardinal implemented daily limits that the pickers and checkers were to use for identifying suspicious orders. Schedules of these limits were implemented across the entire United States in the late 1990’s. The charts identify daily limits for multiple drugs including several categories of opioids for Cardinal Health customers.

833. According to Cardinal Health’s top regulatory employee from 1996 to 2007, Steve Reardon, any orders exceeding these limits should have been stopped, reported to the DEA, and due diligence should have been conducted and documented to dispel suspicion of diversion before

³⁰⁴ CAH_MDL_PRIORPROD_DEA07_01176559

³⁰⁵ CAH_MDL_PRIORPROD_DEA07_01384040; CAH_MDL_PRIORPROD_DEA07_01176607

³⁰⁶ CAH_MDL_PRIORPROD_DEA07_01188147.

³⁰⁷ CAH_MDL_PRIORPROD_DEA07_01383895.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

the order was allowed to ship.³⁰⁸ This was never done for orders going to Plaintiffs' Community or the rest of West Virginia.

834. The warehouse employees at each distribution center had the impossible task of monitoring the millions of orders received each month by Cardinal, comparing those orders to the Dosage Limit Chart, and reporting any excessive orders to the DEA. Cardinal documents show that in a single month in 2009, for example, Cardinal shipped more than 146 million dosage units of fentanyl, hydromorphone, methadone, morphine, oxycodone, and oxymorphone dosage units across United States.³⁰⁹ This procedure simply was not followed at Cardinal Health to any meaningful degree. In fact, Cardinal Health did not report a single excessive order pursuant to this policy at its Wheeling, West Virginia distribution center, which distributes to Cabell County, as well as the rest of West Virginia.

835. From at least 1996 to 2008 Cardinal's other method for reporting suspicious orders was through the submission of Ingredient Limit Reports (ILR) to the DEA. These were retrospective monthly summaries for the prior month related to all controlled substances including opioids. These reports showed which orders of controlled substances Cardinal received that exceeded a pre-determined average that had been multiplied by 4. Cardinal's submission of ILRs did not satisfy its obligation to report suspicious orders under 21 C.F.R. 1301.74(b) as they were only submitted after the orders had already shipped. Cardinal knew the reports did not satisfy Cardinal's suspicious order reporting obligations because both the DEA and the National Wholesale Druggists Association – predecessor of the Healthcare Distribution Alliance – had made it clear as early as 1984 that they did not. In an April 27, 1984 letter to NWDA Vice President of Government Affairs, Ronald Streck, Acting Chief of the Diversion Operations Section of the

³⁰⁸ Depo. of Reardon, 421:4-16; 493:1-18

³⁰⁹ CAH_MDL2804_03248526

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

DEA, G. Thomas Gitchell, advised Streck that an “after-the-fact computer printout of sales data does not relieve a registrant of its responsibility to report excessive or suspicious orders when discovered.”³¹⁰ The NWDA’s Suspicious Order Monitoring System guidelines, issued to all its members including Cardinal Health in June of 1993, re-states the DEA’s position, advising distributors that the “submission of a monthly printout of after-the-fact sales will not relieve a registrant from the responsibility of reporting these single excessive or suspicious orders.”³¹¹ In other words, it was Cardinal’s policy to ship orders it knew were suspicious without conducting any due diligence or investigation. Further, the ILR system failed because it did not account for orders of unusual frequency or orders deviating from a normal pattern. Despite having around 30,000 employees, Cardinal Health had only 3 employees that were responsible for reviewing Ingredient Limit Reports.³¹² Even Cardinal Health’s former Vice President of Quality and Regulatory Affairs, Steve Reardon, testified that three individuals was insufficient to review all Ingredient Limit Reports.³¹³

836. Cardinal Health has been in possession of the *NWDA Suspicious Order Monitoring System* (v.1984), including the “Letters from the DEA Approving the Format” since 1993.³¹⁴ Cardinal Health was on notice that “after-the-fact computer printout of sales data” is not sufficient to comply with federal regulations. Nonetheless, Cardinal Health continued to report suspicious orders after-the-fact.

837. Cardinal Health has been in possession of Section 5126 of the DEA’s Diversion Investigators Manual (v.1996) since at least 2003.³¹⁵ The Manual states:

³¹⁰ CAH_MDL2804_01465723, 01465732.

³¹¹ *Id.* at 01465730.

³¹² Depo. of Reardon, 71:16-72:5; 147:14-21.

³¹³ *Id.* at 464:4-20.

³¹⁴ CAH_MDL2804_01465723.

³¹⁵ CAH_MDL2804_02203353.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

The supplier can determine whether the order is excessive by checking their own sales and establishing the average amount of controlled substances shipped to registrants of the same apparent size in a particular geographic area. If the customer exceeds this threshold, the request should be viewed as suspicious. This activity, over. Extended periods of time, would lead a reasonable person to believe that controlled substances possibly are being diverted.

838. Cardinal Health was on notice that shipping a suspicious order, rather than blocking the order, expressed an “attitude of irresponsibility that is a detriment to public health and safety.” Nonetheless, Cardinal Health continued to ship suspicious orders.

839. Cardinal Health met with the DEA on August 22, 2005, as part of the DEA’s Distributor Initiative.³¹⁶ Cardinal Health was reminded to “report suspicious orders when discovered” and that “reporting a suspicious order to DEA does NOT relieve the distributor of the responsibility to maintain effective control against diversion.” Nonetheless, Cardinal Health continued to ship suspicious orders and report after-the-fact. For instance, at the end of July 2007, Cardinal Health sent to the DEA a 535 page Ingredient Limit Report for its Wheeling distribution facility which documented each pharmacy which ordered more than 4x the average base weight of controlled substances.³¹⁷ The July 2007 IRL flagged The Medicine Shoppe in Huntington (WV). Cardinal Health converted the number of pills into a base weight of oxycodone and “reported” to the DEA that it had shipped The Medicine Shoppe 363 grams of oxycodone. Cardinal health’s ingredient limit for oxycodone was 116 grams (which was 4x the average pharmacy). Cardinal Health shipped to The Medicine Shoppe more than 12x the average customer in July 2007.³¹⁸

840. In 2008, for the first time, Cardinal implemented a written policy to stop shipment of orders suspected of diversion. The policy was implemented more than a year following the

³¹⁶ US-DEA-00000352.

³¹⁷ CAH_MDL_PRIORPROD_DEA07_01120515.

³¹⁸ By June 12, 2012, internal Cardinal Health communications referred to The Medicine Shoppe as a “black hole.” CAH_MDL2804_03309972. Nonetheless, Cardinal Health continued to ship opium pills to this customer.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

receipt of Joseph Rannazzisi's September 27, 2006 letter reminding Cardinal of its obligation to stop shipments of suspicious orders. As Cardinal Health's own employee Steve Reardon testified, suspicious orders must not be shipped without first conducting due diligence to dispel the suspicion of diversion.³¹⁹

841. Prior to 2012 Cardinal Health's approach to reporting suspicious orders was to only report customers that appeared suspicious enough to warrant Cardinal terminating the customer as an unreasonable risk for diversion.³²⁰

842. In 2007 the DEA initiated a prosecution of multiple Cardinal Health distribution centers due to their failure to operate an adequate suspicious order monitoring systems (SOMS) and violations of the CSA. The DEA found that Cardinal Health failed to "maintain adequate controls against the diversion of controlled substances on or prior to September 30, 2008, at all distribution facilities" operated, owned, or controlled by Cardinal Health in the United States. This encompassed all 27 of Cardinal Health's distribution facilities.

843. Cardinal Health knew its suspicious order monitoring system (SOMS) was defective. In the face of sanctions from the DEA, Cardinal Health commissioned Cegedim Dendrite to perform an investigation into its suspicious order monitoring system (SOMS). The report, dated January 23, 2008, found that Cardinal Health's SOMS was not compliant with federal law and made several recommendations. Cardinal Health did not timely implement many of the recommendations.³²¹

³¹⁹ Depo. of Steve Reardon, 451:15-23.

³²⁰ CAH_MDL_PRIORPROD_HOUSE_0003331.

³²¹ CAH_MDL2804_03309960. Cardinal Health failed to disclose this external investigation and/or its findings in its "confidential" written response to Congress despite a specific directive from the Chief Counsel of Oversight and Investigations, Committee on Energy and Commerce, United States House of Representatives. CAH_MDL_PRIORPROD_HOUSE_0004068.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

844. Cardinal Health then entered into an Administrative Memorandum of Agreement, following the DEA's issuance of immediate suspension orders or orders to show cause ("ISO" or "OSC") on Cardinal distribution centers in Washington, Florida, New Jersey, and Texas.³²² Cardinal distributed massive amounts of opioids to pharmacies across the country that Cardinal knew or should have known were diverting opioids. The DEA found that Cardinal failed to maintain effective controls to detect and prevent diversion of controlled substances at each distribution center.

845. Some examples of the conduct which the DEA found to be systemic across the United States includes:

- a. The DEA found that Cardinal's Auburn, Washington distribution center distributed in excess of 600,000 dosage units of hydrocodone over seven months to its largest customer, Horen's Drugstore, which was a "rogue drugstore" filling illegitimate prescriptions from internet pharmacies.³²³
- b. Cardinal Health's Lakeland, Florida distribution center was found to have distributed over 8,000,000 dosage units of combination hydrocodone products to pharmacies Cardinal knew or should have known were diverting opioids.³²⁴ At that time, retail pharmacies in Florida averaged less than 8,400 dosage units per month.³²⁵ Cardinal shipped many, many times that average to Florida pharmacies it knew or should have known were diverting opioids.
- c. The DEA found that Cardinal's Swedesboro, New Jersey distribution center had distributed 4.5 million dosage units of hydrocodone products to customers it new or should have known were diverting the drug.³²⁶
- d. Finally, the DEA found that Cardinal's Stafford, Texas distribution center distributed almost 21 million dosage units of hydrocodone to retail pharmacy customers "under circumstances that clearly indicated that the pharmacies were engaged in the widespread diversion of controlled substances," frequently distributed hydrocodone in excess of 800 dosage units per day without reporting

³²² CAH_MDL_PRIORPROD_DEA12_00013056.

³²³ *Id.* at 00013071-00013072.

³²⁴ *Id.* at 00013075.

³²⁵ *Id.* at 00013076.

³²⁶ *Id.* at 00013080.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

these incidents to the DEA or conducting any investigation, which violated Cardinal's own policy.³²⁷

846. Cardinal paid \$34 million to the U.S. government to resolve the investigation and was also required to implement a suspicious order monitoring program wherein it would determine whether a suspicious order should either not be filled and reported to the DEA or based on a detailed review the order is for a legitimate purpose and not likely to be diverted - obligations with which Cardinal Health did not comply.

847. In light of the DEA crackdown in 2007, Cardinal hired Deloitte to create a threshold system, which set thresholds for each base code for each customer based on 1) the customer's designation as small, medium, or large (based on the customer's sales), 2) the average orders for the prior year of all customers in that size designation, and 3) multiplied by a factor of three. Deloitte's calculation of initial thresholds was based on the previous twelve months' worth of ordering data. These numbers were significantly inflated due to the fact the United States was in the middle of a deadly opioid epidemic. Almost immediately Cardinal began increasing thresholds far and above the levels established by Deloitte. Cardinal Health took no steps to consider the opioid epidemic when setting or increasing these thresholds.

848. Due in part to Cardinal's history of failing to monitor, detect, and report suspicious orders, average distribution of opioids had increased dramatically across the country over the previous decade. Cardinal calculated the thresholds amid the opioid epidemic, benefiting from an artificially high average upon which to base its calculations. These thresholds, which would become the centerpiece of Cardinal's anti-diversion program going forward, were premised on faulty reasoning.

³²⁷ *Id.* at 00013085-6.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

849. Under Cardinal's threshold system after 2008, according to its Standard Operating Procedures, if for a given month a customer ordered more than its established threshold, Cardinal would be notified, the order would be held, and a due diligence review of the customer's profile and order history was triggered. Cardinal employees have testified that if an order tripped a pharmacy's threshold, a review of the circumstances surrounding the order should be documented and maintained in that pharmacy's "due diligence file." According to Cardinal's policies neither the orders triggering the pharmacy's threshold nor any other orders for drugs from the same drug family should have been shipped to the pharmacy without first conducting due diligence to verify that the orders were not suspicious. Cardinal documents show that in spite of its policies, Cardinal continued to fill orders for the same controlled substances without regard to the prior threshold breaches. Cardinal failed to conduct due diligence in response to these threshold events. Cardinal also continued to ship the customer the same drug that triggered a threshold event without any evidence that the order had been investigated or that the suspicion had been dispelled.

850. Cardinal had a policy and practice of providing preferential treatment to chain pharmacies differently than retail-independent pharmacies, in many respects, including setting thresholds and conducting due diligence. Cardinal Health refused to impose the same requirements on chain customers because, as stated in Cardinal's June 27, 2006 letter to the New York Attorney General, large, national chains can "take their billions upon billions of dollars in business to any wholesaler in the country."³²⁸ Cardinal did not calculate thresholds for chain pharmacies in the same manner as described above; instead, this was a process that was conducted outside the Anti-Diversion Department at Cardinal Health. Cardinal also failed to conduct due diligence on its retail pharmacy chain customers, and instead, relied on the chains to report this information. Former

³²⁸ 89(5) FOIL Appeal G000804 000006.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

Cardinal Health Director of Supply Chain Integrity, Steve Morse, confirmed this practice, particularly with respect to CVS.³²⁹ Morse testified that despite Cardinal's written policy of requiring pharmacies to provide drug utilization reports, sales of controlled substances, sales of non-controlled substances, or prescriber information, and that a pharmacy's refusal to provide such information would be a red flag, CVS failed to provide this information to Cardinal. Despite the clear violation of Cardinal's own policies, Cardinal continued to supply CVS stores with huge volumes of opioids.

851. After 2008, Cardinal ceased submitting Ingredient Limit Reports as its suspicious order reports but continued to manually submit suspicious order reports. Cardinal documents indicate that, nationwide, Cardinal reported a few dozen suspicious orders per year from 2008 to 2011.³³⁰ The Baltimore, Maryland DEA office found that between 2008 and October 1, 2011, Cardinal's Swedesboro, New Jersey distribution center failed to report any suspicious orders.³³¹ In 2012, the DEA began another prosecution of Cardinal Health for "blatantly" violating the terms of its 2008 MOU and shipping suspicious orders.³³²

852. The DEA served another ISO on Cardinal's distribution facility in Lakeland, Florida – one of the facilities at issue in the 2008 action – for distributing excessive amounts of oxycodone to retail pharmacies. Steve Morse, who Cardinal hired following the 2008 DEA action, was demoted for failing to timely terminate the pharmacies despite finding evidence of suspected diversion. Morse was removed from his position as a Director of Investigations to a position in regulatory management. A 2013 report of the Special Demand Committee of Cardinal Health's

³²⁹ Deposition of Steve Morse, 113:8-13.

³³⁰ CAH_MDL2804_03262274, 03262438, CAH_MDL2804_00228327 and 00228364.

³³¹ CAH_MDL2804_02509732, 02509741.

³³² Prevoznik Dep. (DEA 30(b)(6) designee), Vol. II, p.193 (April 19, 2019)

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

Board of Directors cited his questionable judgment as part of the reason for this demotion and the fact that Morse failed to review pharmacy site visit report as required by Cardinal's 2008 SOPs.³³³ Similar to Steve Morse, as a result of the 2012 ISO and DEA investigation, Mr. Moné was moved from his position as Vice President of Anti-Diversion into a position as an attorney with the company's regulatory group where he remains today as a VP Associate General Counsel. The Special Demand Committee report states that Mr. Moné was moved as part of Cardinal's transition to "assessing customers based more on objective criteria;" under Moné evaluation of customers was a subjective standard.³³⁴

853. The 2012 DEA investigation resulted in Cardinal Health admitting that it failed to ensure proper due diligence for its customers and in complying with the 2008 MOA. The DEA has testified, through Thomas Prevoznik, that the DEA is "in fact frustrated that registrants were blatantly violating the MOUs from prior administrative actions" including "Cardinal Health's 2008 MOU and settlement which resulted in a second DEA fine."³³⁵ It is this type of blatant disregard for regulatory obligations that has made the current volume of pills available to the public at large.

854. Cardinal Health entered a second MOA with the DEA in 2012 (2012 MOA) and again assured the DEA that they would come into compliance and operate within the confines of the CSA. Cardinal Health indicated that this time it was going to get it right and remove all subjectivity from the process to prevent poor decision making.

855. While Cardinal Health again attempted to make changes to its SOMS systems it still did not ensure that it was maintaining effective controls to prevent the diversion of controlled

³³³ CAH_MDL_PRIORPROD_HOUSE_00003331, 0003367.

³³⁴ CAH_MDL_PRIORPROD_HOUSE_0003331, 0003367.

³³⁵ See Prevoznik Dep. Vol. II, 621:5 to 621:20, April 18, 2019 (DEA 30(b)(6) designee)

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

substances. Cardinal Health continued to operate with the same threshold system that was previously in operation, with several changes.

856. Around the same time Cardinal Health entered into the 2012 MOA with the DEA it moved Todd Cameron into the position of Senior Vice-President of Supply Chain Integrity. Mr. Cameron has testified that Cardinal Health's new threshold system focused on prescription volume of each specific customer to determine its threshold. The significant problem with this approach was that Cardinal Health no long considered population or comparison to similarly situated customers when setting thresholds.

857. While that lack of ensuring proper due diligence on chains such as CVS and Walgreens was a significant issue related to the 2012 MOA, Cardinal Health continued to refuse to require the same due diligence from national chains as they did retail independents.³³⁶ Additionally, Cardinal Health's failure to ensure its chain customers were conducting due diligence was further aggravated by the fact that Cardinal Health failed to sufficiently evaluate the national chains' SOMS to determine if it such programs were effective to prevent diversion.³³⁷

858.

859. Cardinal Health also devised a system where pharmacy customers were provided buffers above their previously set thresholds and used a coding scheme to identify which pharmacies had this built-in buffering system. However, Cardinal Health made no mention of any such buffering system in its SOP's that were the policies Cardinal Health indicated to regulators, including the DEA, it was operating by.

860. Even after the 2012 DEA investigation, Cardinal Health continued to fail to report suspicious orders. Cardinal Health Director of Quality and Regulatory Affairs Chris Forst testified

³³⁶ CAH_MDL2804_02953715

³³⁷ CAH_MDL2804_02953716

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

that after 2012, Cardinal Health only reported orders that the company believed to present a “high potential for diversion” instead of orders of unusual size, of unusual frequency, or deviating substantially from a normal pattern.³³⁸ From 2012 through 2015 Cardinal Health admittedly failed to report approximately 14,000 suspicious orders from “across the country” to the DEA.³³⁹ The “vast majority” of those orders involved opioids. Cardinal Health “uncovered” the unreported suspicious orders retrospectively through an audit process in 2015.³⁴⁰

iii. McKESSON

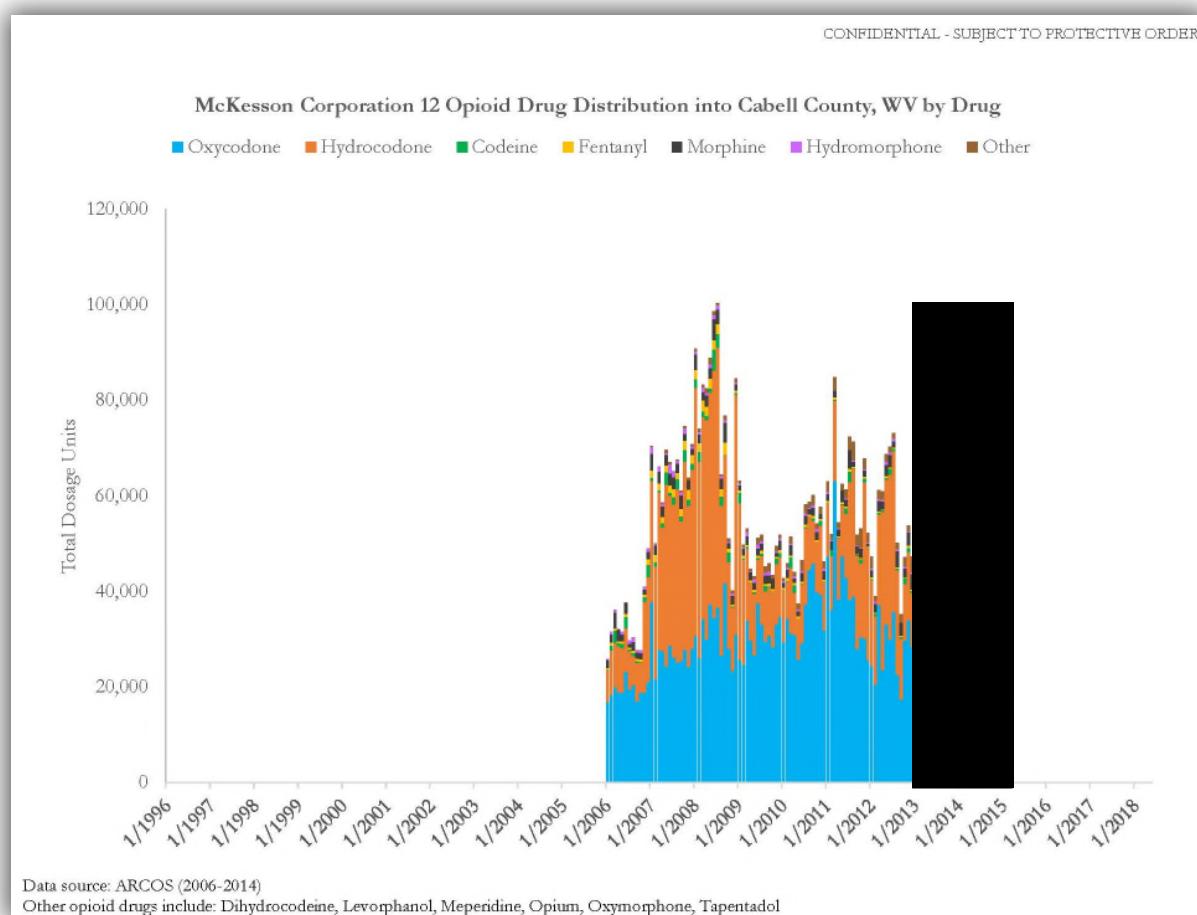
861. Defendant McKesson breached its duties under federal and state law.

862. As shown by the ARCos Data, McKesson distributed an extraordinary amount of prescription opioids into Plaintiffs’ Community. McKesson’s excessive distribution was made possible by, and is evidence of, McKesson’s failures to comply with its duties under state and federal law, including the CSA.

³³⁸ Depo. of Christ Forst, 192:15-193:4.

³³⁹ Depo. of Todd Cameron, 269:12-270:13.

³⁴⁰ *Id.* at 271:18-22.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

863. McKesson failed to meet its suspicious order monitoring requirements, failed to stop shipment on suspicious orders, and failed to effectively prevent diversion in breach of its duties under state and federal law. These breaches contributed substantially to the public nuisance and harms alleged in the Plaintiffs' Community.

864. McKesson is a sophisticated pharmaceutical distributor that has amassed great wealth from the delivery of pharmaceutical products, including prescription opioids. In fact, McKesson touts the fact that it delivers 1 out of every 3 prescriptions in the United States.³⁴¹ This prowess in the pharmaceutical arena currently has McKesson seated at number 6 on the Fortune

³⁴¹ MCKMDL00336768 at MCKMDL00336776

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

500 list. However, as the company acknowledges, its size and infiltration into various aspects of the pharmaceutical industry have also provided the company with a unique national perspective on the diversion of controlled substances, including opioids.³⁴²

865. McKesson has admitted its well-established duties under the Controlled Substances Act (hereinafter “CSA”) to prevent diversion through its monitoring of controlled substances, which has been consistent since 1970.³⁴³ As part of this suspicious order monitoring system, McKesson has a duty to report suspicious orders and to halt shipment of any orders that are deemed suspicious.³⁴⁴ Further, McKesson has conceded that violations of these CSA requirements result in a substantial and detrimental effect on the health and general welfare of the American people.³⁴⁵

866. Importantly, McKesson has also known since it began distributing opioids that this class of drugs has a high potential for abuse, and can lead to severe psychological and physical dependence.³⁴⁶ In fact, McKesson has acknowledged in internal presentations that the opioid epidemic is the deadliest drug epidemic this country has ever faced.³⁴⁷ Unfortunately, opioid addiction is also a direct gateway to the initiation of illicit heroin use.³⁴⁸ Therefore, the prescription opioid epidemic has only served to spawn additional epidemics.

867. McKesson admits that the societal costs of the opioid epidemic have been massive. McKesson internally has estimated that financial impact to cost this country in the range of \$57

³⁴² MCKMDL00452353 at MCKMDL00452357

³⁴³ See 7/31/18 Hartle Depo. at 78:4-10; 85:2-9

³⁴⁴ See 7/31/18 Hartle Depo. at 36:14-37:4; 38:5-19

³⁴⁵ See 7/31/18 Hartle Depo. at 43:22-44:5

³⁴⁶ See 7/31/18 Hartle Depo. at 50:3-7; 50:22-51:3

³⁴⁷ MCKMDL00448596 at MCKMDL00448598

³⁴⁸ See 8/1/18 Hartle Depo. at 37:4-38:17

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

billion annually.³⁴⁹ McKesson has further conceded that McKesson is partially responsible for the societal costs of the opioid epidemic this country faces today.³⁵⁰

868. McKesson has consistently failed to comply with its obligations under the CSA. McKesson has had SOM policies in place dating at least back to 1997.³⁵¹ Under this policy, which remained in effect until 2007, a daily and monthly Controlled Substance Suspicious Order Warning Report was generated at the distribution center. To qualify for placement on this report the controlled substance order had to be 3 times the rolling 12 month average for that drug at that distribution center.³⁵² While McKesson claims that these reports were provided to the DEA, McKesson has not yet provided any evidence that this claim is true. Further, orders listed on this report were not held or halted, but were shipped without review. McKesson's own regulatory employees have conceded that these reports did not satisfy the requirements of the CSA to report suspicious orders.³⁵³

869. In late 2005, DEA began investigating McKesson for filling large quantities of hydrocodone and oxycodone orders for internet pharmacies. In January 2006, DEA notified McKesson that it had identified more than 2 million doses of hydrocodone delivered by McKesson to several internet pharmacies during a 3 week period.³⁵⁴ During discussions with DEA, McKesson conceded that these extremely large orders were not flagged, in part, because McKesson did not track the sale of generic drugs for suspicious order monitoring purposes.³⁵⁵ These excessive and suspicious purchases ultimately led to DEA seeking a show cause order against the distribution

³⁴⁹ MCKMDL00336833 at MCKMDL00336856

³⁵⁰ See 7/31/18 Hartle Depo. at 285:6-286:15

³⁵¹ MCKMDL00651873

³⁵² MCKMDL00346554 at MCKMDL00346582; *See also* Gary Hilliard Depo. at 163:21-169:7

³⁵³ MCKMDL00510747; *See also* Gary Hilliard Depo. at 176:8-22

³⁵⁴ MCKMDL00496876 at MCKMDL00496877

³⁵⁵ MCKMDL00496876 at MCKMDL00496877 - MCKMDL00496878

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

center supplying these pills. McKesson ultimately resolved these violations as part of the 2008 settlement.³⁵⁶

870. Due in large part to the violations referenced above, in May 2007 McKesson created the Lifestyle Drug Monitoring Program (“LDMP”). The LDMP set thresholds of 8,000 doses a month for oxycodone and hydrocodone containing products.³⁵⁷ However, these thresholds were only “soft caps,” and orders exceeding these levels would not be blocked and were not reported to DEA.³⁵⁸ Additional problems with the LDMP were uncovered during routine auditing of the program. First, it was noted that “it is possible not all of the products containing one of the generic ingredients are included” in the reports generated as part of the LDMP.³⁵⁹ The second flaw noted was that the Daily Dosage Summary Report generated under the LDMP was organized by distribution center, and therefore a customer could both exceed the monthly 8,000 dosage unit threshold and avoid detection by spreading its purchases across multiple distribution centers.³⁶⁰ McKesson employees have alleged the company continued using the DU45 reports during this time period to report excessive orders as defined above.

871. While McKesson’s first written policy aimed at preventing diversion dates back to at least 1997, the company has shown an unwillingness to comply with that policy and those that followed it. By 2008, the DEA and DOJ felt compelled to punish McKesson for its flagrant non-compliance with the CSA. On May 2, 2008, McKesson entered into a settlement agreement with the DEA and DOJ and paid \$13,250,000 in fines for numerous violations of the CSA concerning the distribution of opioids.³⁶¹ The scope of the violations at issue were sprawling. The settlement

³⁵⁶ MCKMDL00337001 at MCKMDL00337013

³⁵⁷ MCKMDL00330211

³⁵⁸ MCKMDL00540033

³⁵⁹ MCKMDL00591949 at MCKMDL00591951

³⁶⁰ MCKMDL00591949 at MCKMDL00591951

³⁶¹ MCKMDL00337001

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

covered conduct occurring at distribution centers in Maryland, Florida, Texas, Colorado, Utah, and California.³⁶²

872. The violations at issue were as egregious as they were widespread. For example, from January 2005 to October 2006 McKesson delivered over 3,000,000 doses of hydrocodone to a single small pharmacy in Baltimore, Maryland while also failing to report any of the orders from that pharmacy as suspicious.³⁶³ In a single month, McKesson delivered more than 2 million doses of hydrocodone to seven pharmacies in the Tampa area and failed to report any orders from those pharmacies as suspicious.³⁶⁴ Over a several month period in 2007 McKesson delivered 2.6 million doses of hydrocodone to two Texas pharmacies while failing to report any orders from those pharmacies as suspicious.³⁶⁵ These violations only scratch the surface of the conduct at issue in the 2008 settlement agreement.

873. In May 2008, McKesson launched the Controlled Substances Monitoring Program (“CSMP”). The CSMP has remained in effect in some form since 2008. Given that the CSMP was created as a result of the DOJ settlement, it would be expected that the program would serve to make it more difficult for customers to improperly obtain opioids. However, when the program was launched McKesson made sure to notify all of its pharmacy customers that it would remain “business as usual” as it pertained to those customers’ ability to obtain controlled substances, including opioids.³⁶⁶

874. Thresholds were set under the CSMP utilizing the customer’s last 12 months of orders for a given product and adding a buffer to that amount. Specifically, McKesson took the

³⁶² MCKMDL00337001 at MCKMDL00337013 - MCKMDL00337014

³⁶³ MCKMDL00337001 at MCKMDL00337013

³⁶⁴ MCKMDL00337001 at MCKMDL00337013

³⁶⁵ MCKMDL00337001 at MCKMDL00337013

³⁶⁶ MCKMDL00543554 at MCKMDL00543558

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

highest of the preceding 12 months orders for a given product and added a 10% buffer to that number and set that as the running threshold for the customer.³⁶⁷ Retail national accounts received even more leeway on their thresholds generally being given a 20-25% buffer, rather than 10%.³⁶⁸ Thresholds were also routinely increased with little or no justification given to support the increase.³⁶⁹ Customers were also notified as they approached their threshold, so they could request an increase without any interruption in receiving the product.

875. While customers rarely reached their thresholds under the CSMP, if they did the orders would be blocked until a threshold increase was approved. Once the orders were blocked under the CSMP a three-level review was also triggered.³⁷⁰ This three-level review was designed to assess whether the order was suspicious and whether further orders from the customer should be blocked. Orders were only reported as suspicious if the review made it to level 3.

876. The settlement with DEA & DOJ in 2008 and the implementation of the CSMP program did nothing to curb McKesson’s flagrant violations of the CSA.

877. The DEA has testified that McKesson “blatantly” violated the terms of its 2008 MOU with the DEA.³⁷¹

878. The DEA and DOJ began investigating McKesson again in 2013 and quickly discovered that McKesson had developed a policy of not reporting suspicious orders. In fact, the CSMP in effect actually instructed McKesson employees to avoid using the word suspicious so as to avoid the requirement to report suspicious orders to the DEA.³⁷² This policy, and others, ensured that McKesson reported almost no suspicious orders of opioids nationally from 2008 to 2013.

³⁶⁷ MCKMDL00267223 at MCKMDL00267225

³⁶⁸ MCKMDL00430124

³⁶⁹ MCKMDL00476776

³⁷⁰ MCKMDL00000021 at MCKMDL00000029 - MCKMDL00000031

³⁷¹ See Prevosnik Dep. Vol. II, 621:5 to 621:16, 624:13 to 624:18, April 18, 2019 (DEA 30(b)(6) designee).

³⁷² MCKMDL00002509 at MCKMDL00002531

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

879. McKesson also manipulated the threshold system it established to ensure that it would not have to block customer orders or engage in any due diligence involving customer orders. First, McKesson set thresholds so high that they would never be exceeded thus ensuring that no higher level due diligence would be required by McKesson.³⁷³ Second, McKesson would routinely increase opioid thresholds preemptively despite a well-established policy that threshold increases should always be customer generated.³⁷⁴ Third, McKesson would also increase thresholds for the flimsiest of reasons or for no reason at all. For example, in November 2008, employees of McKesson permanently increased opioid thresholds for 200 customers by 30% for no reason other than it was around the Thanksgiving holidays.³⁷⁵

880. McKesson also deferred completely to retail national account customers to dictate when their thresholds would be increased. McKesson's Senior Director of Distribution Operations, Donald Walker, readily acknowledged that McKesson did not ask for dispensing data in order to verify the legitimacy of threshold increases for retail national account customers and generally deferred to those customers to decide when it was appropriate for them to get threshold increases for controlled substances.³⁷⁶ For example, as seen in a January 2009 presentation, McKesson outlined its plan for automatic threshold increases for CVS stores when they approached their threshold and to only seek a justification for thresholds increases from CVS if the increases were "extraordinary" and without "further CVS explanation."³⁷⁷ McKesson's erroneous reasoning for such automatic threshold increases was to "minimize disruption of business," and to ignore reviewing "routine" threshold increases.³⁷⁸

³⁷³ MCKMDL00409224 at MCKMDL00409234

³⁷⁴ MCKMDL00409224 at MCKMDL00409235

³⁷⁵ MCKMDL00000520

³⁷⁶ See Donald Walker Depo. at 190-193

³⁷⁷ MCKMDL00574488

³⁷⁸ MCKMDL00574488

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

881. Ultimately, DEA and DOJ concluded that McKesson's desire for increased sales and retaining its customers overrode its obligations to report suspicious orders and jeopardized the health and safety of people around the country.³⁷⁹ DEA and DOJ described McKesson's due diligence failures as to opioids as both "nationwide" and "systemic".³⁸⁰ As a result of these broad sweeping due diligence failures, McKesson agreed to a \$150,000,000 settlement with the DEA and DOJ.³⁸¹ Additionally, McKesson accepted responsibility for nationwide failures of due diligence as to opioid distribution spanning 2009 to 2017.³⁸² It would be expected that such a harsh financial penalty would have dramatically altered McKesson's practices. However, before the ink of the settlement agreement was even dry, McKesson was already re-assuring customers who were concerned that the flow of opioids would be curtailed that it would be "business as usual" at McKesson.³⁸³

882. After renewed investigations by the DEA and DOJ beginning in late 2013, McKesson began to try and tighten up its SOM policies. Included within those efforts was the threshold reduction initiative wherein McKesson reduced the oxycodone thresholds for most customers, which ultimately resulted in a total threshold reduction for oxycodone of 42 million doses per month.³⁸⁴

883. McKesson also began working with a consulting company named Analysis Group ("AGI") in 2014. AGI was tasked with creating a new SOM policy for McKesson. AGI and McKesson tinkered around with some advanced analytics over the next couple of years until finally settling into a new analytics-based program in 2017. Under this new system, McKesson

³⁷⁹ MCKMDL00409224 at MCKMDL00409234

³⁸⁰ MCKMDL00409453 at MCKMDL00409454

³⁸¹ MCKMDL00355349

³⁸² MCKMDL00355349 at MCKMDL00355352

³⁸³ MCKMDL00418094

³⁸⁴ MCKMDL00410744 & MCKMDL00402184

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

established two separate thresholds – the benchmark threshold and the same-customer threshold. The lower of these two thresholds was binding on the customer as their operative threshold.³⁸⁵ The same customer threshold is simply a threshold created based on the customer order history for the product in question. That threshold changes monthly as a new average is established for the customer.³⁸⁶ The benchmark threshold is established by inputting factors such as size of the pharmacy and typical usage for the geographic region whether the pharmacy is located.³⁸⁷ Orders exceeding these thresholds are blocked and reported to DEA.³⁸⁸

884. On January 5, 2017, McKesson entered into an Administrative Memorandum Agreement with the DEA wherein it agreed to pay a \$150 million civil penalty for, *inter alia*, failure to identify and report suspicious orders at its facilities in Aurora, CO; Aurora, IL; Delran, NJ; LaCrosse, WI; Lakeland FL; Landover, MD; La Vista, NE; Livonia, MI; Methuen, MA; Santa Fe Springs, CA; Washington Courthouse, OH; and West Sacramento, CA. McKesson admitted that, at various times during the period from January 1, 2009 through the effective date of the Agreement (January 17, 2017) it “did not identify or report to [the] DEA certain orders placed by certain pharmacies which should have been detected by McKesson as suspicious based on the guidance contained in the DEA Letters.”

McKesson further admitted that, during this time period, it “failed to maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific and industrial channels by sales to certain of its customers in violation of the CSA and the CSA’s implementing regulations, 21 C.F.R. Part 1300 et seq., at the McKesson Distribution Centers” throughout the United States. Due to these violations, McKesson agreed to a partial suspension of its authority to distribute controlled substances from certain of its facilities some of which, investigators found “were supplying pharmacies that sold to criminal drug rings.”

³⁸⁵ MCKMDL00336634 at MCKMDL00336679

³⁸⁶ MCKMDL00336634 at MCKMDL00336687

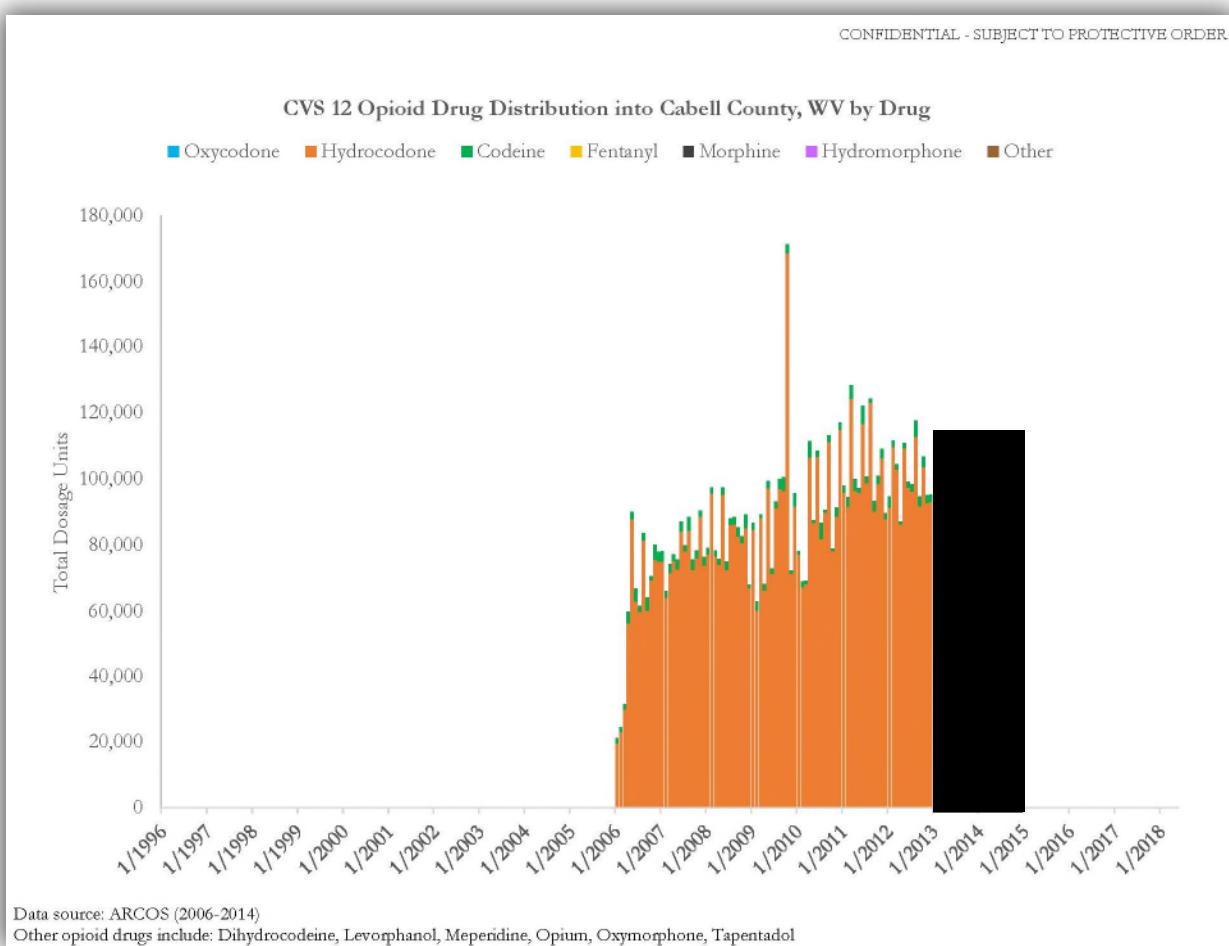
³⁸⁷ MCKMDL00336634 at MCKMDL00336683

³⁸⁸ MCKMDL00336634 at MCKMDL00336682

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER**iv. CVS**

885. Defendant CVS breached its duties under federal and state law.

886. As shown by the ARCos Data, CVS distributed an extraordinary amount of prescription opioids into Plaintiffs' Community. CVS's excessive distribution was made possible by, and is evidence of, CVS's failures to comply with its duties under state and federal law, including the CSA.



887. CVS failed to meet its suspicious order monitoring requirements, failed to stop shipment on suspicious orders, and failed to effectively prevent diversion in breach of its duties

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

under state and federal law. These breaches contributed substantially to the public nuisance and harms alleged in the Plaintiffs' Community.

888. By 2009, CVS Pharmacy, Inc., owned and/or operated more than 9,000 pharmacies in the United States. At all times herein relevant, CVS pharmacies sold controlled substances, including FDA Schedule II and FDA Schedule III controlled substances otherwise known as opiate narcotics or Opioids.

889. Until October 6, 2014, CVS pharmacies ordered and were supplied FDA Schedule III hydrocodone combination products (HCPs) from a combination of outside vendors and CVS distribution centers. CVS pharmacies also received Schedule II opioids from outside vendors, including Cardinal and McKesson.

890. CVS Pharmacy, Inc. instituted, set-up, ran, directed and staffed with its own employees the majority of the SOM functions for its distribution and dispensing arms.

891. Prior to December 2008, CVS relied primarily upon a SOM system of "pickers and packers" as its primary suspicious order monitoring system. These CVS distribution center employees worked within CVS distribution centers to pick orders of multiple items including controlled substances ordered by thousands of CVS retail pharmacies. The pickers and packers system was an ineffective and deficient SOM system.

892. Additionally, during this time period CVS also relied upon a SOM system of what it called "PDMR/ Viper" reports. The PDMR/Viper report was not a SOM tool or a viable part of an effective SOM system, and did not provide any sufficient data that would help to identify a specific controlled substances order that was of unusual size, deviating substantially from a normal pattern and/or unusual frequency.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

893. In early/mid 2009 CVS instituted a SOM program based upon a set of algorithms that on a daily basis would flag suspicious orders that needed additional investigation.

894. The output of the flagged orders was called an Item Review Report (IRR).

895. The IRR system was deficient and failed in many respects. The IRR system failed to meet CVS's obligations as a distributor of HCPs.

896. All orders that appeared on the IRR should have been subjected to a thorough due diligence investigation but only a very small percentage were subjected to appropriate due diligence investigation.

897. Effective due diligence tools were lacking during much of the relevant time period. Additionally, even after the introduction of what could have been appropriate due diligence tools such as the store metrics report in late 2012, this report used outdated data which for the most part made the analysis irrelevant, pointless and ineffective.

898. Recognizing the ineffectiveness and deficiencies within its SOM system, CVS hired consultants in 2012 to troubleshoot its existing SOM systems for the purpose of either fixing the deficient system or developing a new SOM system. CVS delayed those efforts and failed to dedicate sufficient resources to immediately repair and retool and run an effective SOM system while the Opioid crisis continued to escalate. The new SOM system did not was not fully implemented at CVS until mid to late 2014.

899. Prior to October 2014, CVS reported very few suspicious orders to the DEA despite a continuing and ever-increasing epidemic of diversion and abuse of controlled substances distributed and sold by CVS distribution centers and CVS pharmacies.

900. Based upon information and belief, Plaintiffs believe that, prior to 2012, CVS failed to report any suspicious orders to the DEA for any CT2 pharmacy.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

901. At all times herein relevant, CVS pharmacies have ordered and been supplied Schedule II controlled substances, including Schedule II opioids, from outside vendors, including Defendants McKesson and Cardinal.

902. CVS pharmacies made CVS Pharmacy, Inc. the largest customer of both McKesson and Cardinal.

903. From 2006 to 2014, CVS Pharmacies, Inc. accounted for approximately 22% of Cardinal's annual revenue through the purchases made by CVS pharmacies. This equated to paying Cardinal Health over \$20 Billion dollars annually. Currently CVS Pharmacy, Inc provides 25% of the revenue to Cardinal Health, **over \$34 Billion dollars.**

904. Cardinal and McKesson failed to sufficiently inspect or confirm the effectiveness of CVS's alleged SOM program or perform due diligence regarding that program.

905. In reality, the Viper system was not a suspicious order monitoring program. CVS's 30(b)(6) witness Mark Vernazza admitted at deposition that Viper "was not deemed a SOM report." Viper was no more than a theft report that provided no ability to evaluate specific orders of controlled substances placed by CVS pharmacies to Cardinal Health. In reality, CVS had no policies, procedures or programs to monitor prescription opioid orders placed by its pharmacies to Cardinal Health or any other outside vendor until at least 2014.

906. Turning a blind eye to the ineffectiveness of CVS's controlled substance monitoring program, Cardinal Health shirked its nondelegable duty and gave its "proxy" to CVS headquarters to perform due diligence investigations of potentially suspicious orders and individual CVS pharmacies that were ordering excessive amounts of prescription opioids. Cardinal Health inquiries concerning suspicious orders and activities of individual CVS pharmacies were made to Defendant CVS Pharmacy, Inc. and not to individual CVS pharmacies. Cardinal Health

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

left the decision of whether to ship opioids to CVS pharmacies to the conflicted and non-existent due diligence efforts, and flawed findings of CVS.³⁸⁹

907. McKesson similarly blindly and improperly delegated its responsibility to monitor suspicious orders and to perform due diligence investigations of potentially suspicious orders to CVS. McKesson made inquiries concerning suspicious orders and activities of individual CVS pharmacies directly to CVS Pharmacy, Inc. and not to individual CVS pharmacies. McKesson relied upon the “due diligence efforts” and findings of CVS Pharmacy, Inc. in its decision to ship opioids to CVS pharmacies.

908. Appropriate and acceptable due diligence and monitoring would have stopped said orders and prevented the diversion of prescription opioids at CVS pharmacies.

909. Contrary to the representations of CVS Pharmacy, Inc., it did not have a prescription opioid monitoring program relating to outside vendors, including McKesson and Cardinal, until 2014. Until the implementation of a new SOM system in 2014, CVS did not even monitor prescription opioid orders placed with outside vendors from its pharmacies.

910. McKesson and Cardinal knew they were not receiving information necessary to establish appropriate thresholds and to perform effective due diligence on potentially suspicious orders themselves from CVS. Despite knowing that they did not have the necessary information or access, McKesson and Cardinal continued to ship to CVS.

911. Additionally, prescription opioid threshold increases and overrides for CVS pharmacies were readily given by Cardinal Health without appropriate due diligence, with blind reliance upon CVS representations of internal regulatory controls.³⁹⁰

³⁸⁹ CAH-MDL2804_01115446.

³⁹⁰ CAH_MDL_PRIORPROD DEA12_00011836, CAH_MDL_PRIORPROD DEA12_00011853, CAH_MDL_PRIORPROD DEA07_00159466, CAH_MDL_PRIORPROD DEA12_00004383.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

912. Cardinal Health also knew that it did not have access to significant information necessary to perform sufficient due diligence of CVS orders. Despite knowing it did not have access to the information necessary to evaluate the orders, Cardinal Health continued to ship to CVS.

913. CVS effectively assumed the duties and responsibilities for the monitoring of prescription opioid orders distributed from both McKesson and Cardinal to CVS pharmacies throughout the United States, including West Virginia and Plaintiffs' Community specifically.

914. CVS failed in its assumed duty to make reasonable efforts to maintain effective controls against diversion of controlled substances and to monitor suspicious orders of controlled substances placed by CVS pharmacies to McKesson and Cardinal. Said failure resulted in the shipment of prescription opioids to CVS pharmacies throughout the United States that should not have occurred and ultimately resulted in the diversion of prescription opioids into the Plaintiffs' Community.

915. In the alternative, McKesson, Cardinal and CVS conspired to orchestrate and carry out a plan that allowed the distribution of prescription opioids to CVS pharmacies from McKesson and Cardinal, without any effective controls against diversion or suspicious order monitoring in violation of the legal obligations of CVS, McKesson and Cardinal. Said conspiracy caused the diversion of prescription opioids into the Plaintiffs' Community.

916. Further, though CVS had access to significant information about red flags due to its vertical integration with its stores, CVS failed to use available information indicating red flags in order to more effectively prevent diversion.

917. As a National Pharmacy, CVS knew or should have known that its pharmacies in the Tri-State area were (a) filling multiple prescriptions to the same patient using the same doctor

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

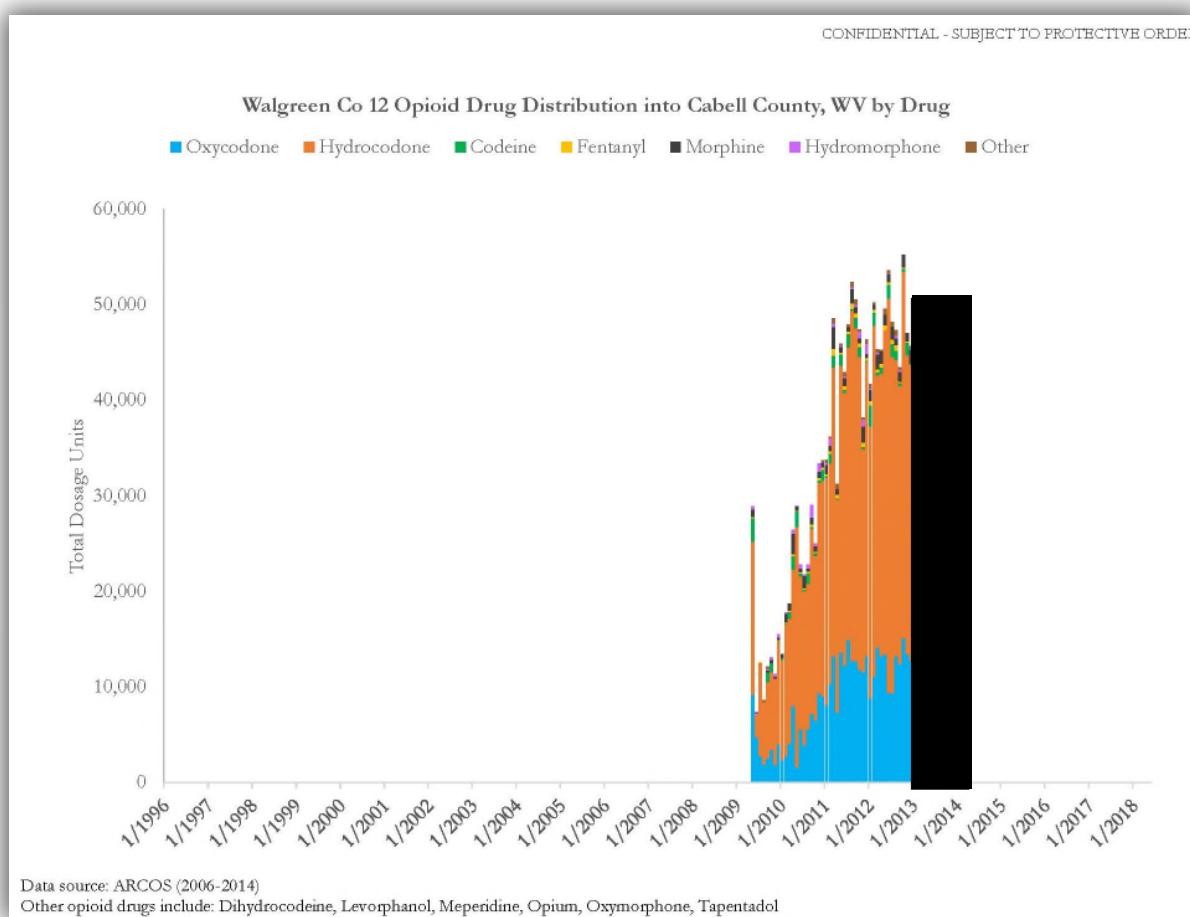
(b) filling multiple prescriptions by the same patient using different doctors (c) filling orders of unusual size and frequency for the same patient (d) filling orders of unusual size and frequency from out-of-state patients; (e) filling orders of unusual size and frequency paid for in cash (f) filling orders of unusual size and frequency from the same prescribing physician (g) filling orders of unusual size and frequency from out-of-state physicians.

918. Because of its vertically integrated structure, CVS has access to complete information regarding red flags of diversion across its pharmacies in and around Plaintiffs' Community, but CVS failed to utilize this information to effectively prevent diversion, both as a Distributor and as a National Pharmacy.

v. WALGREENS

919. Defendant Walgreens breached its duties under federal and state law.

920. As shown by the ARCos Data, Walgreens distributed an extraordinary amount of prescription opioids into Plaintiffs' Community. Walgreens's excessive distribution was made possible by, and is evidence of, Walgreens's failures to comply with its duties under state and federal law.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

921. Walgreens failed to meet its suspicious order monitoring requirements, failed to stop shipment on suspicious orders, and failed to effectively prevent diversion in breach of its duties under state and federal law. These breaches contributed substantially to the public nuisance and harms alleged in the Plaintiff's community.

922. As a distributor, from 2010 – 2014, Walgreens distributed [REDACTED] dosage units of hydrocodone and oxycodone into two Cabell County Walgreens stores, Stores No. 11977 and 11980.

923. During the same time period, Walgreens also dispensed [REDACTED] dosage units of hydrocodone and oxycodone through the same two Cabell County Walgreens stores.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

924. Prior to beginning distribution into Plaintiffs' Community, Walgreens knew that its SOM system did not comply with its CSA obligations. In May 2006, the DEA sent Walgreens a Letter of Admonition citing Walgreens for controlled substances violations at its Perrysburg Distribution Center. Specifically, the DEA informed Walgreens that the "formulation utilized by the firm for reporting suspicious ordering of controlled substances was insufficient,"³⁹¹ and "inadequate." The DEA reminded Walgreens that its suspicious ordering "formula should be based on (size, pattern, frequency)." ³⁹²

925. After receiving the Letter of Admonishment, Walgreens decided to utilize the "three times" formula outlined in Appendix E-3 of the Chemical Handler's Manual to generate and send the DEA a monthly report of "Suspicious Control Drug Orders" that Walgreens had filled for its stores.³⁹³ Walgreens sent these post-shipment "Suspicious Control Drug Orders" reports to the DEA from 2007 through 2012. Despite the orders being flagged for being "suspicious," Walgreens did not halt these orders or perform any due diligence on them before shipment.³⁹⁴ Walgreens did not perform the size, pattern, and frequency analysis prescribed by the DEA, but merely used this "three times" formula to list the orders on an after the fact report and then continued shipping.

926. Walgreens knew that this type of post-shipment "excessive purchase report" did not satisfy the requirements of 21 C.F.R. § 1301.74(b). In September 2007, three Walgreens's senior employees (Dwayne Pinon, Senior Attorney; James Van Overbake, Auditor; and Irene Lerin, Audit Manager) attended the DEA Office of Diversion Control's 13th Pharmaceutical

³⁹¹ *Id.*

³⁹² WAGMDL00709508.

³⁹³ WAGMDL00400357.

³⁹⁴ See Errata to E. Bratton 30(b)(6) deposition.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

Industry Conference in Houston, Texas.³⁹⁵ Michael Mapes, Chief, DEA, Regulatory Section, gave a presentation at this Conference relating to suspicious orders, which included the reminder that the CSA “requirement is to report suspicious orders, not suspicious sales after the fact.”³⁹⁶ Participant notes from this meeting indicate that Mr. Mapes advised the audience not to “confuse suspicious order report with an excessive purchase report. They are two different things.”³⁹⁷

927. Despite knowing as early as 2006 that its SOM policies were inadequate, being admonished by the DEA, and receiving specific instruction that the post-shipment excessive purchase reports did not satisfy its duties, Walgreens still did not institute a SOM program.³⁹⁸

928. It was not until March 2008, in response to three of Cardinal Health’s DCs being shut down by the DEA for suspicious drug ordering violations, that Walgreens finally took action to “begin creating” a SOM program.³⁹⁹

929. In December 2008, Walgreens conducted an internal audit of its Perrysburg, OH Distribution Center. That audit found that issues related to Walgreens suspicious controlled drug order processing and reporting system were still open from DEA’s May 2006 inspection, but kicked the can down the road and set meeting for five months later to discuss an updated methodology.⁴⁰⁰

³⁹⁵ CAH_MDL_PRIORPROD_DEA07_01185382 at CAH_MDL_PRIORPROD_DEA07_01185404-5.

³⁹⁶ CAH_MDL_PRIORPROD_DEA12_00011059; HDS_MDL_00002032 at 2040.

³⁹⁷ Acquired_Actavis_00441354 at 441355.

³⁹⁸ WAGMDL00757193 (“internal controls that ensure compliance with DEA regulations … pertain[ing] to all company DCs … should be addressed to void potential DEA sanctions”, noting that these issues had been pending and “un-remediated” since audits in 2005 and 2006, and included “suspicious controlled drug order processing and reporting” and “lack of formalized CII controlled substance policies and procedures.”); *See also* WAGMDL00709508 (“suspicious ordering report is inadequate”); WAGMDL00709510 (“formulation utilized by the firm for reporting suspicious ordering of controlled substances was insufficient”).

³⁹⁹ WAGMDL00659801 at 818; WAGMDL00709395.

⁴⁰⁰ WAGMDL00757193.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

930. Though Walgreens developed a SOMS algorithm in June 2008,⁴⁰¹ Walgreens did not practically begin to implement its SOM program until August 2009, when it began to pilot the algorithm with respect to orders from seven (7) Walgreens stores.⁴⁰² The algorithm reviewed some (but not all) orders for controlled substances that these seven Walgreens stores placed to Walgreens Distribution Centers and flagged them based on “tolerance” (size of the order) and “frequency” (how often the orders were placed).

931. Until September 2010, the SOM program flagged certain orders that exceeded the tolerance or frequency thresholds as “suspicious,” but did not reduce, block, or report the orders. In September 2010, the program began to reduce orders that exceeded the tolerance threshold set by Walgreens to an amount below the threshold, but still did not halt the orders for evaluation or report the orders as suspicious. In November 2012, the program began to automatically reduce orders that violated ceiling thresholds.⁴⁰³ Still, the program did not halt the orders for due diligence evaluation or report the orders as suspicious.

932. The DEA has clearly stated that cutting orders that exceed a threshold to a lower volume and then shipping them without review is a violation of a distributor’s duties under the CSA. Further, there is no evidence that these flagged or cut orders were reported as suspicious to the regulatory authorities.

933. Not only did Walgreens’s SOM program not halt or report the orders its SOM program flagged as being suspicious, but there were other loopholes that limited the program’s effectiveness. First, the program only monitored orders Walgreens stores placed to Walgreens’s own distribution centers, so that even if a store hit its ceiling with Walgreens, the store could order

⁴⁰¹ WAGMDL00624527.

⁴⁰² WAGMDL00667936, at 938 and 940; *see also* WAGMDL00658227.

⁴⁰³ WAGMDL00667938.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

more controlled substances through outside vendors such as Cardinal Health.⁴⁰⁴ Second, even though a Walgreens store had hit its ceiling limit, the SOM program permitted stores to place PDQ (“pretty darn quick”) orders for controlled substances outside of those limits.⁴⁰⁵ Additionally, stores had the ability to “interstore,” which means they simply transferred product from another store outside of the visibility of the SOM program.⁴⁰⁶ Beginning in 2013, Walgreens finally implemented the process of which in theory only permitted stores to order controlled substances in excess of the thresholds if such orders could be justified. However, the review process was nominal, as such requests were almost always approved, as evidenced by the 95%+ approval rate for FY 2014 and 2015.⁴⁰⁷

934. Walgreens admits that, since at least 2009, the DEA had instructed Walgreens to “stop what was considered suspicious drug shipments to any of our stores.”⁴⁰⁸ However, Walgreens continued to ship all flagged orders without due diligence review and continued to merely send a report to the DEA regarding all orders triggered by the Appendix E-3 Chemical Handler’s test. This remained Walgreens’s practice until the end of 2012.

935. On April 7, 2011, Walgreens entered into a Settlement Agreement with DEA regarding allegations of non-compliance with the Controlled Substance Act related to Walgreens’s dispensing activities wherein Walgreens had agreed to “maintain a compliance program to detect and prevent diversion of controlled substances.”⁴⁰⁹

⁴⁰⁴ See N. Polster Deposition at 250:1-253:7.

⁴⁰⁵ WAGMDL00705321.

⁴⁰⁶ See N. Polster Deposition at 257:14-258:2.

⁴⁰⁷ WAGMDL00010887.

⁴⁰⁸ WAGMDL00660331.

⁴⁰⁹ See Walgreens 2013 MOA (WAGMDL00490963-WAGMDL00490978; WAGMDL00387975-WAGMDL00387982; WAGMDL00387653-WAGMDL00387974) at WAGMDL00387975.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

936. In April 2012, the DEA served a Subpoena and a Warrant of Inspection on one of Walgreens's three Schedule 2 controlled substance distribution centers, the Jupiter Distribution Center, seeking all controlled substance SOPs, communications about controlled substances, customer due diligence files for 14 Walgreens stores, and all records related to distribution of controlled substances.⁴¹⁰

937. After the DEA instituted its regulatory investigation, Walgreens engaged in meetings with the DEA about Walgreens's "Controlled Substance Anti-Diversion and Compliance Program" in an effort to "cooperate and avoid litigation," and represented to the DEA that it was making "new changes" to "enhance" its SOMS program.⁴¹¹ Internally Walgreens claimed that it enhanced its SOMS program "in an effort to convince DEA that the proposed penalty is excessive..."⁴¹²

938. After reviewing the materials provided by Walgreens in response to the April 2012 subpoenas, on September 13, 2012, the DEA issued an Order to Show Cause (OTCS) and Immediate Suspension of Registration (ISO) to Walgreens on the basis that the Jupiter Distribution Center constituted "an imminent danger to the public health and safety" and ordered that Jupiter's controlled substance vault be sealed.⁴¹³ The DEA alleged that Walgreens's Jupiter DC failed to comply with DEA regulations that required it to report to the DEA suspicious drug orders that Walgreens received from its retail pharmacies. Further, the DEA alleged that Walgreens's failure

⁴¹⁰ WAGMDL00777158; CAH_MDL2804_01431069 at 01431074.

⁴¹¹ WAGMDL00659801 at 802.

⁴¹² WAGMDL00659270.

⁴¹³ See Settlement and Memorandum of Agreement between the Department of Justice, DEA, and Walgreens Co., with appendices (collectively, "Walgreens 2013 MOA") (WAGMDL00490963-WAGMDL00490978; WAGMDL00387975-WAGMDL00387982; WAGMDL00387653-WAGMDL00387974) at WAGMDL00387654 (Letter from Michele Leonhart to Walgreen Company, *Order to Show Cause and Immediate Suspension of Registration* (Sept. 13, 2012), ["Jupiter Show Cause Order"]).

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

to sufficiently report suspicious orders was a systemic practice that resulted in at least tens of thousands of violations, particularly concerning massive volumes of prescription opiates.

939. Documents revealed as a result of the regulatory investigation show that Walgreens's own distribution centers were questioning how Walgreens stores could even shelve the number of bottles of prescription opioids they were ordering and that Florida law enforcement officials were making dozens of drug arrests in Walgreens's parking lots. These same documents reveal that many of the prescriptions being filled were from out of state, including many from the West Virginia, Kentucky, and Ohio Tri-State area.

940. As a result of the DEA investigation, Walgreens formed the Pharmaceutical Integrity ("RX Integrity") group in 2012 to purportedly address Walgreens's SOM noncompliance. However, the group it viewed its real role as protecting the DCs and stores from losing their DEA licenses.⁴¹⁴ The effort was only for show. Walgreens never provided RX Integrity with the necessary resources to perform adequate due diligence on the overwhelming number of orders identified by Walgreens's SOM algorithm for Walgreens's 5,000 plus stores.⁴¹⁵ In December 2012 Walgreens's "updated" SOM program resulted in 14,000 flagged orders that required due diligence reviews.⁴¹⁶ At the time these 14,000 orders were flagged, Walgreens's RX Integrity department consisted of fewer than 5 people, and at its height it only had had eleven members.⁴¹⁷ Instead of sufficiently staffing the SOM program, Walgreens noted that it had the ability to control its due diligence workload by simply increasing stores' ceiling values, thereby reducing the number of orders that would breach that ceiling and result in a flag.⁴¹⁸

⁴¹⁴ See WAGMDL00101723; WAGMDL00060486.

⁴¹⁵ See N. Polster Deposition at 133:10-13.

⁴¹⁶ See WAGMDL00659270.

⁴¹⁷ See N. Polster Deposition at 240:3-15.

⁴¹⁸ See WAGMDL00370894 at WAGMDL00414048.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

941. In February 2013, the DEA issued similar Subpoenas and Warrant of Inspection on the Perrysburg Distribution Center in Ohio to those issued to the Jupiter DC in Florida.⁴¹⁹ Walgreens employees made plans in preparation for the Perrysburg DC being “shut down” by the DEA, like the Jupiter DC.⁴²⁰

942. Within weeks of receiving the six subpoenas and warrant, Walgreens decided to “discontinue distribution of controlled substances from the Perrysburg facility” in order to “eliminate any immediate need for further DEA administrative action” regarding the Perrysburg facility.⁴²¹

943. On June 11, 2013 Walgreens entered into a Settlement and Memorandum of Agreement (“MOA”) with the DEA to resolve outstanding allegations involving the Walgreens Distribution Centers and pending actions concerning six Walgreens retail pharmacies located in Florida. Walgreens agreed to pay \$80 million in civil penalties, the largest settlement in DEA history at that time, to resolve the DEA’s claims that Walgreens negligently allowed controlled substances, including oxycodone and other prescription painkillers, to be diverted into the black market.⁴²² In addition to the \$80 million civil penalty, Walgreens agreed to surrender its Jupiter DC’s registration to distribute or dispense controlled substances listed in Schedules II – V for two years from issuance of the Jupiter ISO, ending in 2014. As part of the MOA, Walgreens admitted that its “suspicious order reporting for distribution to certain pharmacies did not meet the standards identified by DEA in three letters from DEA's Deputy Assistant Administrator, Office of Diversion

⁴¹⁹ WAGMDL00493697; WAGMDL00493694.

⁴²⁰ WAGMDL00477975; WAGMDL00358471.

⁴²¹ WAGMDL00674280.

⁴²² See Walgreens 2013 MOA (WAGMDL00490963-WAGMDL00490978; WAGMDL00387975-WAGMDL00387982; WAGMDL00387653-WAGMDL00387974).

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

Control, sent to every registered manufacturer and distributor, including Walgreens, on September 27, 2006, February 7, 2007 and December 27, 2007.” These failures were described as “systemic.”

944. In mid-2013, Walgreens ceased all self-distribution of Schedule II controlled substances. In mid-2014, Walgreens ceased all self-distribution of Schedule III controlled substances. Walgreens instead entered into a business relationship with ABDC through which ABDC would be Walgreens sole distributor and Walgreens would ultimately acquire some 26% of ABDC stock.

945. Though Walgreens had access to significant information about red flags due to its vertical integration with its stores, Walgreens failed to use available information from indicating red flags in order to more effectively prevent diversion.

946. As a National Pharmacy, Walgreens knew or should have known that its pharmacies in the Tri-State area (West Virginia, Ohio, and Kentucky) were (a) filling multiple prescriptions to the same patient using the same doctor (b) filling multiple prescriptions by the same patient using different doctors (c) filling prescriptions of unusual size and frequency for the same patient (d) filling prescriptions of unusual size and frequency from out-of-state patients; (e) filling prescriptions of unusual size and frequency paid for in cash (f) filling prescriptions of unusual size and frequency from the same prescribing physician (g) filling prescriptions of unusual size and frequency from out-of-state physicians; and (h) filing prescriptions for patients and doctors in combinations that were indicative of diversion and abuse. Upon information and belief, the volumes of opioids distributed to and dispensed by these pharmacies were disproportionate to non-controlled drugs and other products sold by these pharmacies, and disproportionate to the sales of opioids in similarly sized pharmacy markets.

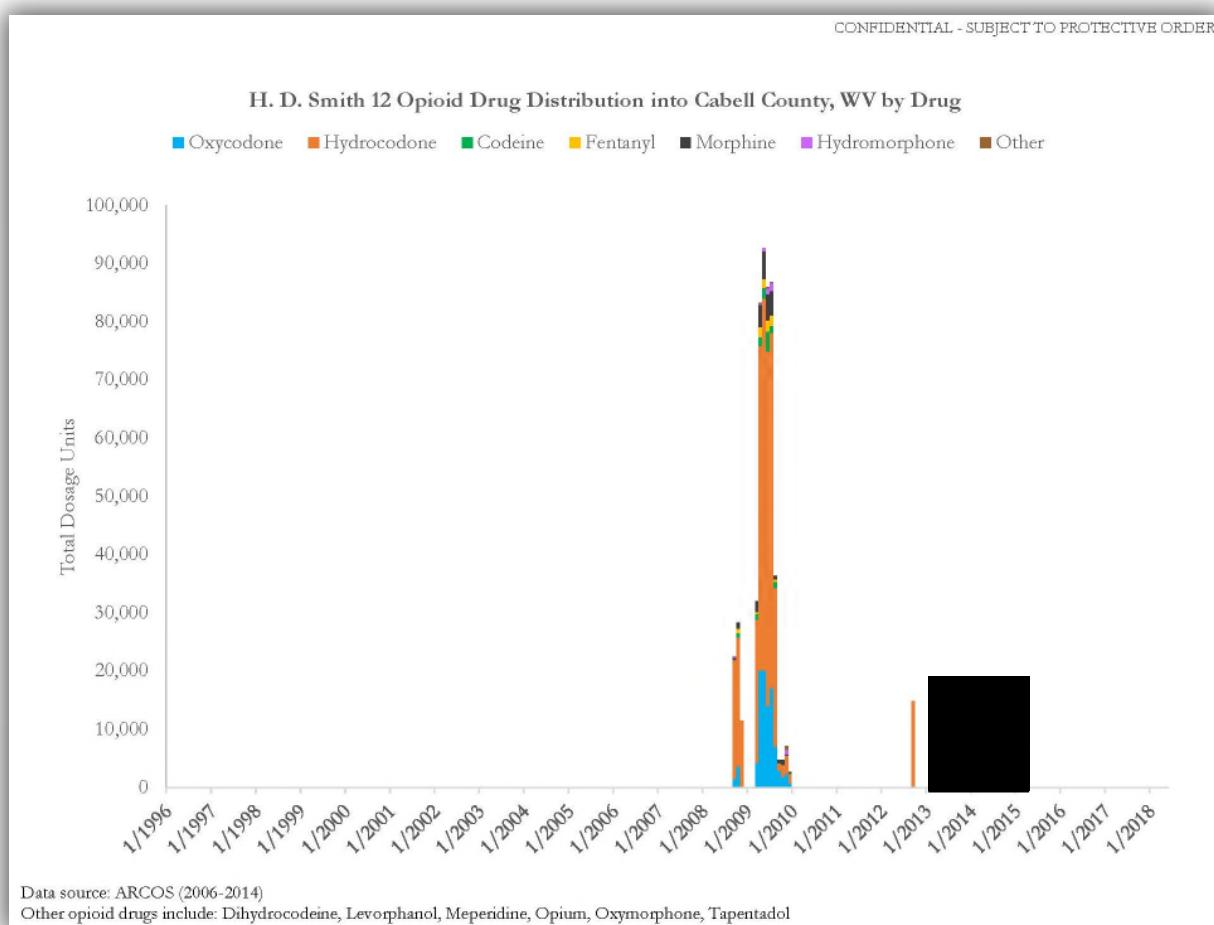
CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

947. Because of its vertically integrated structure, Walgreens has access to complete information regarding red flags of diversion across its pharmacies in and around Plaintiffs' Community, but Walgreens failed to utilize this information to effectively prevent diversion, both as a Distributor and as a National Pharmacy.

vi. H.D. SMITH

948. Defendant H.D. Smith breached its duties under federal and state law.

949. As shown by the ARCos Data, H.D. Smith sold an erratic and extraordinary amount of prescription opioids into Plaintiffs' Community. H.D. Smith's noncompliant sales were made possible by, and are evidence of, H.D. Smith's failures to comply with its duties under state and federal controlled substance laws.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

950. As shown by the ARCOS Data, H.D. Smith sold an extraordinary amount of prescription opioids into Plaintiffs' Community. H.D. Smith's noncompliant sales were made possible by, and are evidence of, H.D. Smith's failures to comply with its duties under state and federal controlled substance laws.

951. Through 2008, H.D. Smith only had two undated policies that were at least nominally in place that covered suspicious order monitoring. These policies were little used. The fact that these policies even existed was not well known by many employees of H.D. Smith.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

952. The first of these policies was entitled, “Controlled Substance Monitoring.”⁴²³ This policy laid out specific steps that employees were to take when reviewing suspicious orders. Among other faults with this policy, it provides only for monthly reporting to the DEA. Further, many of the compliance functions are placed in the hands of the sales staff, which is a conflict of interest.

953. The second policy entitled, “Controlled Substances Coordinator,”⁴²⁴ defines the Operations Managers as the Controlled Substances Coordinator. It placed compliance in the hands of pickers, who were expected to bring to the attention of the Controlled Substance Coordinator any order that appeared to be excessive or unusual, without providing them the necessary information to make these assessments.

954. In or around 2008, H.D. Smith began developing a computer based suspicious order monitoring system which H.D. Smith calls CSOMP. This system was largely (and improperly) based on the DEA Chemical Handler’s Manual as a blueprint to determine “thresholds” for pharmacies. The system was utilized a three times multiplier and did not include pattern and frequency as considerations. Another flaw in the program provided for automatic release of all orders by new pharmacies in order for them to “ramp up.” Orders which hit CSOMP limits were automatically released, allowing the customer to build a high-volume sales “history.” Further, hundreds of people within the company had authority to release a held order.

955. In or around 2014, H.D. Smith hired a new compliance officer and began to create an improved CSOMP program because their existing program was not in compliance with DEA requirements.⁴²⁵ The most notable CSOMP fixes and modifications recommended to bring their

⁴²³ See HDS_MDL_00001033.

⁴²⁴ See HDS_MDL_00001035.

⁴²⁵ See HDS_MDL_00302301.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

program into compliance included (a) changing the CSOMP so that if a new controlled drug order comes into CSOMP while another controlled drug order is pended for the same family, the system would hold the second order rather than allowing the second order to go through; (b) substantially reducing the 448 people in the company who had authority to release a CSOMP hold; (c) enhance the CSOMP system to include a filter to detect account orders that deviate substantially from the norms with regard to frequency and/or pattern; and (d) detect and remove multiple account numbers assigned to one customer/DEA number.⁴²⁶

956. After working on the CSOMP enhancement project for over a year, in 2016 the new compliance officer was terminated before the enhancements went into effect. H.D. Smith rehired their former Vice President of Compliance, as of May 31, 2016.

957. Lori Kirbach worked in the Compliance Department at H.D. Smith until she resigned in February of 2015. When she resigned, she participated in an exit interview and what she stated during that interview spoke volumes.⁴²⁷ Ms. Kirbach stated that the main reason she wanted to leave H.D. Smith was because she felt that the company, “Is and has been breaking the law for some time.” She did not understand why this was being tolerated. Specifically, Ms. Kirbach stated that CSOMP had not been working correctly since OPUS Go Live and that no one would listen to compliance personnel when the issue was brought up. She confirmed that, “Compliance is releasing orders that they should not be releasing.”

vii. KROGER

958. Defendant Kroger breached its duties under federal and state law.

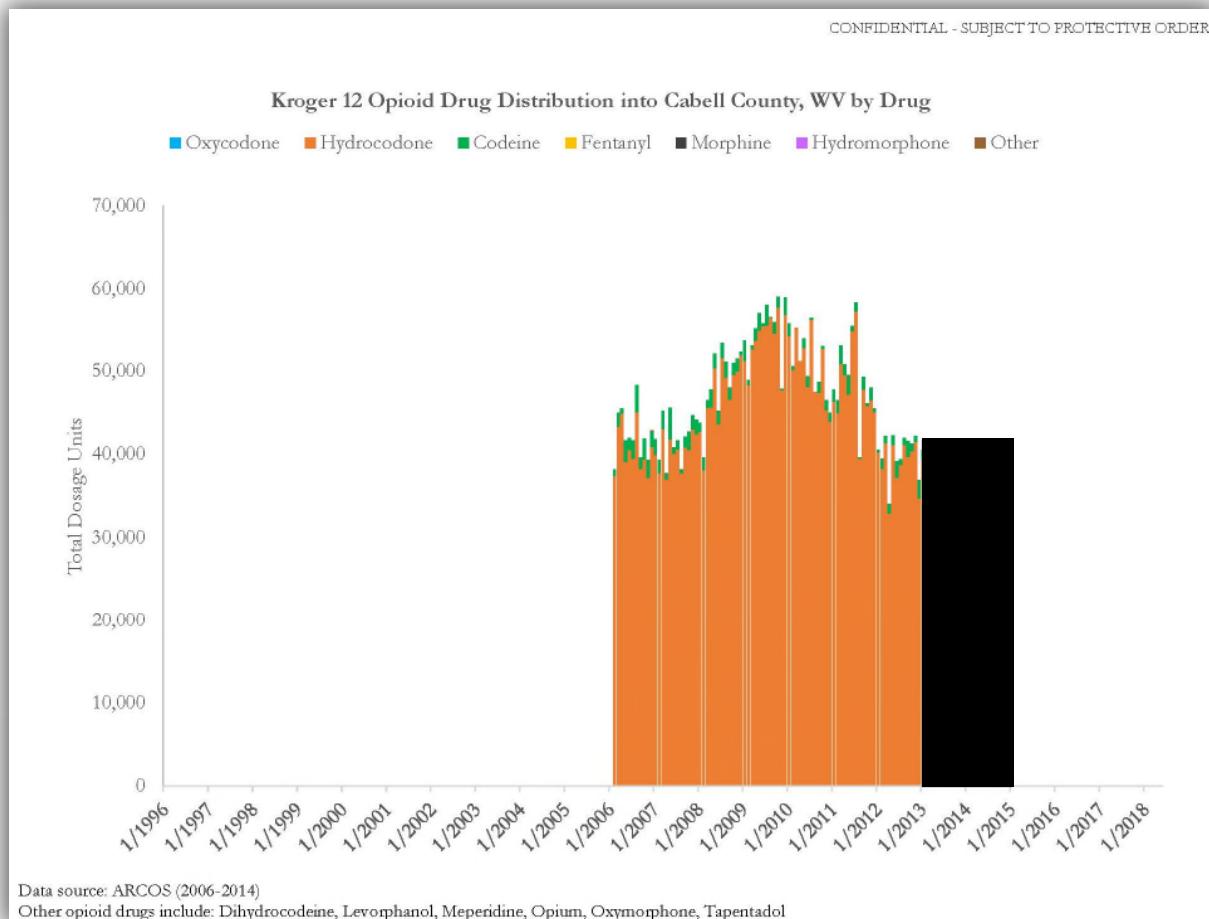
959. As shown by the ARCOS Data, Kroger sold an extraordinary amount of prescription opioids into Plaintiffs’ Community. Kroger’s noncompliant sales were made possible

⁴²⁶ See HDS_MDL_00408717.

⁴²⁷ See HDS_MDL_00510236.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

by, and are evidence of, Kroger's failures to comply with its duties under state and federal controlled substance laws.



960. On information and belief, Kroger failed to implement effective controls against diversion and failed to appropriately monitor for and report suspicious orders, in violation of their duties under federal and state law.

961. On information and belief, though Kroger had access to significant information about red flags due to its vertical integration with its stores, Kroger failed to use available information from indicating red flags in order to more effectively prevent diversion.

962. As a National Pharmacy, Kroger knew or should have known that its pharmacies in the Tri-State area were (a) filling multiple prescriptions to the same patient using the same

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

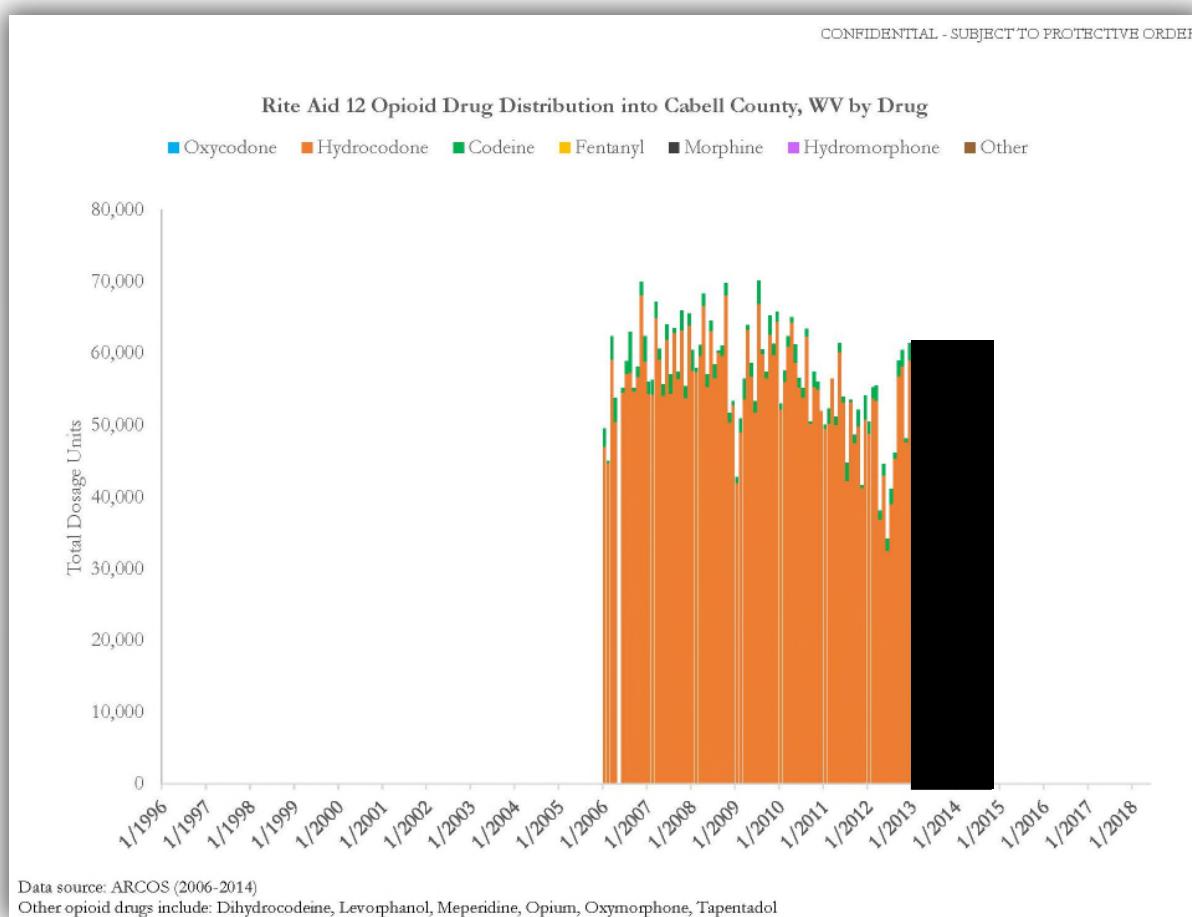
doctor (b) filling multiple prescriptions by the same patient using different doctors (c) filling orders of unusual size and frequency for the same patient (d) filling orders of unusual size and frequency from out-of-state patients; (e) filling orders of unusual size and frequency paid for in cash (f) filling orders of unusual size and frequency from the same prescribing physician (g) filling orders of unusual size and frequency from out-of-state physicians.

963. Because of its vertically integrated structure, Kroger has access to complete information regarding red flags of diversion across its pharmacies in and around Plaintiffs' Community, but, on information and belief, Kroger failed to utilize this information to effectively prevent diversion, both as a Distributor and as a National Pharmacy.

viii. RITE AID

964. Defendant Rite Aid breached its duties under federal and state law.

965. As shown by the ARCos Data, Rite Aid sold an extraordinary amount of prescription opioids into Plaintiffs' Community. Rite Aid's noncompliant sales were made possible by, and are evidence of, Rite Aid's failures to comply with its duties under state and federal controlled substance laws.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

966. As shown by the ARCOS Data, Rite Aid sold an extraordinary amount of prescription opioids into Plaintiffs' Community. Rite Aid's noncompliant sales were made possible by, and are evidence of, Rite Aid's failures to comply with its duties under state and federal controlled substance laws.

967. Rite Aid deliberately disregarded its duties to maintain effective controls and to identify, report, and take steps to halt suspicious orders.

968. At all relevant times, Defendant Rite Aid Corporation established the national policies and procedures governing the Rite Aid system to prevent diversion of controlled substances a nationwide basis including, specifically, West Virginia. Rite Aid Corporation was responsible for directing and implementing policies and procedures governing the distribution and

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

dispensing of controlled substances by its subsidiaries, including but not limited to the Rite Aid Subsidiaries, throughout the United States, including in West Virginia and Plaintiff's Community specifically.

969. Rite Aid failed to effectively control to prevent diversion and failed to report and halt suspicious orders. Rite Aid's SOM system was piecemeal and spread over various non-coordinating departments with poorly defined roles.

970. Rite Aid had no centralized SOM system and, despite significant weaknesses in its system, failed to make substantive improvements or changes to it over time. Rite Aid utilized an auto-replenishment system that did not have the ability to check for red flags and allowed for manual overrides of the generous thresholds. It was "impossible" for this system to detect suspicious orders.

971. The Distribution Centers also were supposed to manually limit orders for any specific drug to 5,000 dosage units a week, if they remembered to do so. Orders which exceeded that size and were caught by the distribution centers were not stopped, but were cut down to 5,000 dosage units and shipped. Rite Aid's "review" of these orders generally just involved calling the store to confirm they meant to place the order.

972. Rite Aid had no parameters, policies, or other guidance about how to determine whether an order was of unusual size, deviated substantially from a normal pattern, or was of unusual frequency – it was at the discretion of the Distribution Center personnel. But Distribution Center employees did not have the ability to determine orders of unusual frequency or deviations from a normal pattern.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

973. The determination of whether an order was “suspicious” and should be reported was left to the Distribution Center employees, who were not given sufficient guidance or resources to make that determination.

974. While the corporate office was to make the determination of whether suspicious orders would be shipped, that policy was moot, as substantially no orders were reported to the corporate office. The corporate office periodically received and reviewed logs of filled orders, but only after shipment.

975. In 2013, Rite Aid corporate embarked on a process to “develop” a SOM system in order to “avoid regulatory fines” and litigation. In the draft policies, Rite Aid recognized that distributors must identify and report suspicious orders based on facts specific to a given customer pharmacy, and not an across the board standard. However, Rite Aid never implemented the new SOM policy because it stopped distributing.

976. Though Rite Aid had access to significant information about red flags due to its vertical integration with its stores, Rite Aid failed to use available information from indicating red flags in order to more effectively prevent diversion.

977. As a National Pharmacy, Rite Aid knew or should have known that its pharmacies in the Tri-State area were (a) filling multiple prescriptions to the same patient using the same doctor (b) filling multiple prescriptions by the same patient using different doctors (c) filling orders of unusual size and frequency for the same patient (d) filling orders of unusual size and frequency from out-of-state patients; (e) filling orders of unusual size and frequency paid for in cash (f) filling orders of unusual size and frequency from the same prescribing physician (g) filling orders of unusual size and frequency from out-of-state physicians.

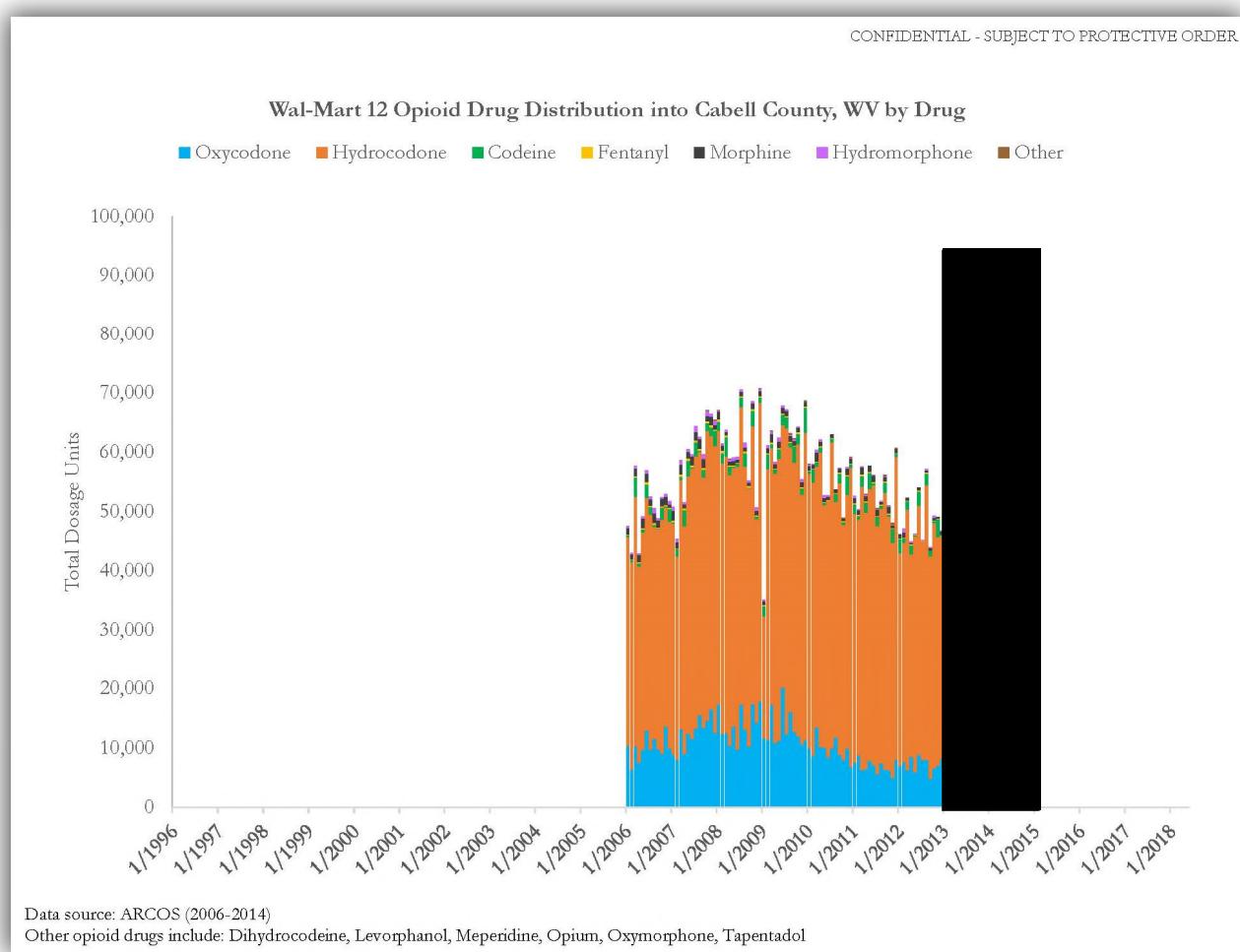
CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

978. Because of its vertically integrated structure, Rite Aid has access to complete information regarding red flags of diversion across its pharmacies in and around Plaintiffs' Community, but Rite Aid failed to utilize this information to effectively prevent diversion, both as a Distributor and as a National Pharmacy.

ix. WALMART

979. Defendant Walmart breached its duties under federal and state law.

980. As shown by the ARCos Data, Walmart sold an extraordinary amount of prescription opioids into Plaintiffs' Community. Walmart's noncompliant sales were made possible by, and are evidence of, Walmart's failures to comply with its duties under state and federal controlled substance laws.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

981. As shown by the ARCOS Data, Walmart sold an extraordinary amount of prescription opioids into Plaintiffs' Community. Walmart's noncompliant sales were made possible by, and are evidence of, Walmart's failures to comply with its duties under state and federal controlled substance laws.

982. From 1996 to 2010, Walmart utilized employees at its distribution centers to review orders for controlled substances, speak to pharmacies about the orders, and escalate any order needing further review. However, Walmart had no written criteria regarding how to identify orders that needed further review. Walmart simply relies on the experience of hourly associates reviewing hundreds of orders each day to recall what an unusual order would be for one of Walmart's more

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

than 4000 pharmacies. Under this system, few, if any orders were ever identified by distribution center employees as needing further review or followed up on.

983. Walmart's policies during this time period failed to identify suspicious orders before shipment or anytime, and, as a consequence, Walmart routinely shipped suspicious orders. Walmart failed to use available reports and information to monitor for suspicious orders. Walmart further did not have a process to monitor or keep track of any order that was flagged.

984. While Walmart faxed "exception reports" to the DEA, these reports were not suspicious order reports and were not used by Walmart to assess suspicious orders.

985. In or around 2011, Walmart implemented order alerts in an inventory management system known as Reddwerks. These alerts flagged orders for controlled substances of 50 bottles or more and orders for amounts 30% higher than a rolling 4 week average for that item. However, this policy included a minimum threshold to this criterion so that even if an order was 30% higher than a rolling 4 week average, it wasn't flagged if the order for that particular product was less than 10 bottles per week.

986. Starting in July 2012 through 2015, Walmart placed a hard limit of 20 bottles of Oxycodone 30 mg, and internally circulated a report listing orders for Schedule II controlled substances of more than 20 bottles for further review and follow-up as needed. Little if any due diligence on these orders was conducted.

987. Walmart also placed a 20-bottle ceiling on oxycodone 30 mg, automatically cutting to 20 bottles and shipping without review any order for more than 20 bottles. While Walmart put at least some of these orders for more than 20 bottles on a list for potential follow up, the orders were still reduced to 20 bottles and shipped.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

988. In November 2017, Walmart started using a third party to flag orders that required further review. Walmart used the third-party system to analyze orders from Walmart pharmacies and flag Orders of Interest, which were reviewed by Walmart's Health & Wellness Practice Compliance personnel. During this time period, Walmart began reporting all Orders of Interest identified using the third-party system to DEA.

989. Walmart conducted very little due diligence during the relevant time period. Even once Walmart put policy in place requiring flagged orders to be reviewed, Walmart failed to follow its own policy and the review of these orders failed to occur.

990. Though Walmart had access to significant information about red flags due to its vertical integration with its stores, Walmart failed to use available information from indicating red flags in order to more effectively prevent diversion.

991. As a National Pharmacy, Walmart knew or should have known that its pharmacies in the Tri-State area were (a) filling multiple prescriptions to the same patient using the same doctor (b) filling multiple prescriptions by the same patient using different doctors (c) filling orders of unusual size and frequency for the same patient (d) filling orders of unusual size and frequency from out-of-state patients; (e) filling orders of unusual size and frequency paid for in cash (f) filling orders of unusual size and frequency from the same prescribing physician (g) filling orders of unusual size and frequency from out-of-state physicians.

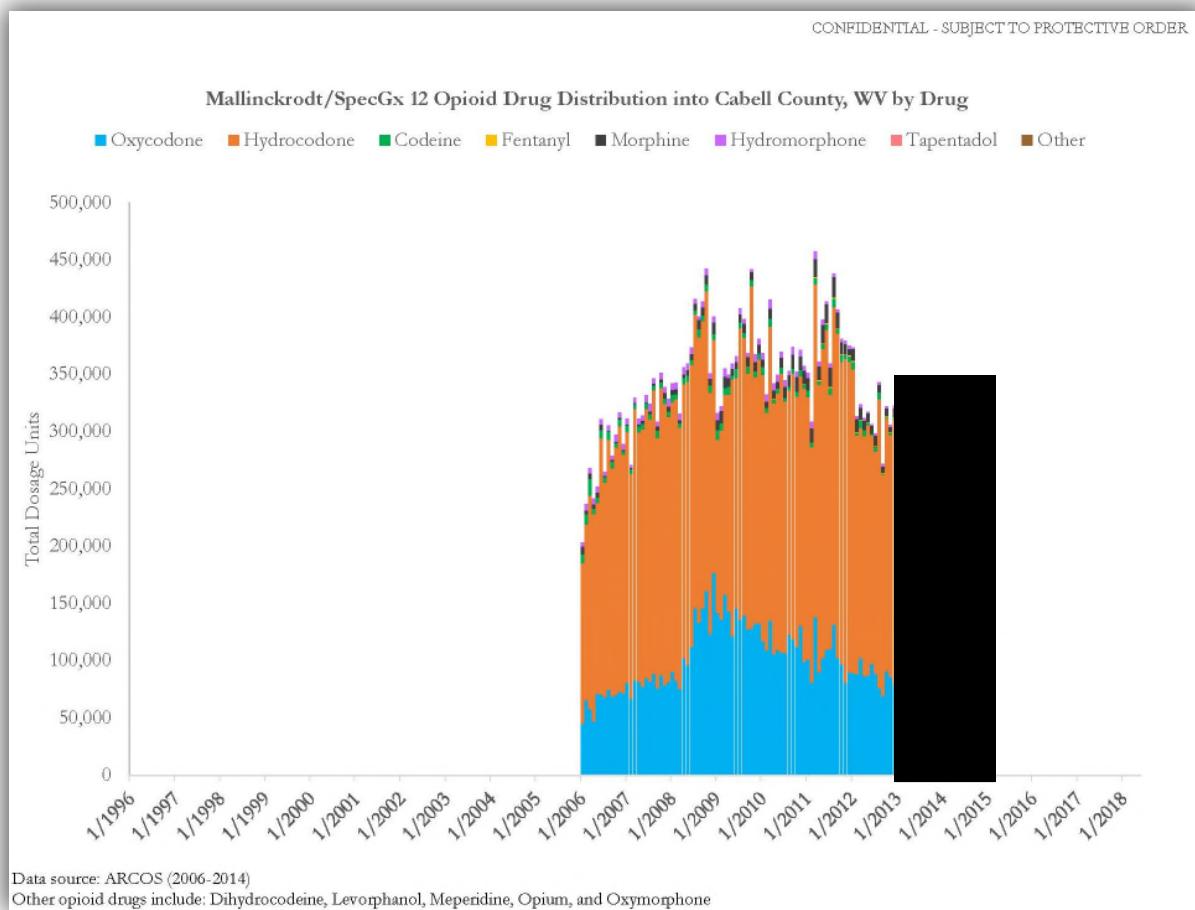
992. Because of its vertically integrated structure, Walmart has access to complete information regarding red flags of diversion across its pharmacies in and around Plaintiffs' Community, but Walmart failed to utilize this information to effectively prevent diversion, both as a Distributor and as a National Pharmacy.

x. MALLINCKRODT

993. Defendant Mallinckrodt breached its duties under federal and state law.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

994. As shown by the ARCOS Data, Mallinckrodt sold an extraordinary amount of prescription opioids into Plaintiffs' Community. Mallinckrodt's excessive sales were made possible by, and are evidence of, Mallinckrodt's failures to comply with its duties under state and federal controlled substance laws.



995. Mallinckrodt failed to meet its suspicious order monitoring requirements, failed to stop shipment on suspicious orders, and failed to effectively prevent diversion in breach of its duties under state and federal law. These breaches contributed substantially to the public nuisance and harms alleged in the Plaintiffs' Community.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

996. Mallinckrodt is one of the largest manufacturers of prescription opioids in the country, with over \$18 billion in sales between 1996 and 2017. Mallinckrodt stoked the fires of the opioid epidemic by shipping hundreds of millions of opioid pills with little regard to where they ended up or how they were used. It is, thus, not surprising that during a meeting with Mallinckrodt in 2010, the DEA referred to the Company as “the kingpin within the drug cartel.”

997. Typifying Mallinckrodt’s attitude toward its duties under the CSA is an email from Victor Borelli, a former Mallinckrodt National Account Manager. In January 2009—a year in which, according to the CDC, over 18,000 people died from opioid overdoses—Mr. Borelli emailed Steve Cochrane, the VP of Sales of wholesale distributor client Keysource Medical to let him know that 1200 bottles of Mallinckrodt oxycodone had been shipped:

“Keep’em comin’! Flyin’ out of there. It’s like people are addicted to these things or something. Oh, wait, people are . . .”

Mr. Borelli responded:

“Just like Doritos, keep eating. We’ll make more.”⁴²⁸

998. Mr. Borelli’s crass response is typical of his communications with Mr. Cochrane. The relationship speaks volumes about Mallinckrodt’s cavalier attitude about the sale of controlled substances. Indeed, Mr. Borelli worked closely with Mr. Cochrane to help him grow his business, notwithstanding obvious red flags. As was the case with several Mallinckrodt wholesale distributor customers, the DEA eventually suspended Keysource Medical’s license to distribute opioids because the company constituted “an imminent danger to public health and safety.” Mallinckrodt ignored this danger—and sold opioids to Keysource and its other wholesale distributor customers up until the day their licenses were suspended by the DEA.

999. Mallinckrodt did not punish or discipline its sales team for selling opioids recklessly to companies that posed an imminent danger to public health and safety. To the contrary,

⁴²⁸ MNK-T1_0000559532

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

Mallinckrodt rewarded them with hefty volume-based bonuses. Between 2008 and 2011, Mallinckrodt flooded Florida with more than 500 million oxycodone pills alone, and Mallinckrodt's director of compliance Karen Harper admitted that she had direct knowledge that these pills were migrating north, including to West Virginia. During this time, Mr. Borelli's bonus went from \$37,904 in 2007 to \$119,096 in 2008, \$101,283 in 2009, \$110,335 in 2010, and \$98,295 in 2011. Another Mallinckrodt National Account Manager, Steve Becker—whose wholesale distributor customers, like Mr. Borelli's, focused on oxycodone and pill mills in Florida—was similarly rewarded. And sales goals followed suit as well, pouring more gasoline on the fire.

1000. Borelli surpassed his 2008 sales objective for Masters Pharmaceuticals by 1,429%, and Mallinckrodt responded not by investigating or monitoring orders, but by setting his 2009 sales objective even higher—indeed, 34 times higher.

1001. Mallinckrodt's poor documentation practices were an impediment to the company's efforts to establish an effective anti-diversion program. Mallinckrodt used the artifice of “peculiar orders” to avoid reporting suspicious orders to the DEA. Mallinckrodt's SOM program was flawed both in its design and implementation rendering it ineffective to detect suspicious orders.

1002. Mallinckrodt did not have a draft written SOM policy until 2008, at the earliest. From 2008 to 2015, Mallinckrodt modified its SOM policies fifteen times, and in 2008, 2011, and 2012, there were three or more revisions per year. Mallinckrodt's approach to its SOM policies and procedures was outside of the norms of good corporate governance and resulted in “drafts” containing gaps and inconsistencies that were used in place of final written standards for years.

1003. Mallinckrodt's SOM program was modified over time as follows:

- a. 2008: Earliest written draft SOM policy – involving simple numerical formula
- b. Fall 2008: discontinued using any formula at all—effectively eliminating its

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

SOM program for a year.

- c. Fall 2009: Reinstated use of numerical formula.
- d. Late 2009 – April 2010: Discontinued aspects of the formula that flagged too many orders.
- e. October 2010: Increased the peculiar order threshold from [REDACTED]
- f. November 2012: Created two tiers - Tier One consisting of a [REDACTED] and Tier 2 [REDACTED] consisting of an algorithm for all other products [REDACTED]
[REDACTED].

1004. Whiles these changes were made to purportedly improve Mallinckrodt's ability to stop suspicious orders, Mallinckrodt simply failed to execute a compliant SOM program. Karen Harper, Mallinckrodt's director of compliance, admitted that revision of the SOM policy was at times a "train wreck." She even admitted that Mallinckrodt released and shipped orders prior to completing due diligence. Moreover, the "due diligence" that Mallinckrodt did conduct was simply to ask the National Account Managers to investigate, and whatever reason the NAM provided for the unusual order pattern was accepted and the order shipped. The results of this blind eye towards identifying and stopping suspicious orders were predictably dismal: from 2003 to 2011, Mallinckrodt shipped a total of 53 million orders, flagged 37,817 as potentially suspicious, and stopped a grand total of 33 orders. This was in the face of skyrocketing sales, including to Florida—a region that was known at the time by Mallinckrodt's own sales managers as the "pill mill capital" of the Country—and Mallinckrodt's direct knowledge that these pills were migrating north to West Virginia.

1005. In addition, despite recognizing by at least 2007 that its chargeback data would allow detailed monitoring of its downstream customers—showing the pharmacy name and DEA registration number, the pharmacy address, and the volume of product—Mallinckrodt's compliance department did not consider using chargeback data at all until 2009. The first effort at systematic use of chargeback data occurred in 2010, but the data was not formally incorporated

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

into Mallinckrodt's SOM policies and procedures until January 2011. Meanwhile, Mallinckrodt continued shipping millions of pills to wholesale distributor customers whose actions screamed diversion.

1006. Harvard Drug Group, a client served first by Borelli and then Becker, is a case in point. On 12,487 occasions, Harvard Drug Group, dba First Veterinary Supply sold oxycodone 15 and 30 to pain clinics, dispensing physicians, and pharmacies—over 88% of which were in Florida. Mallinckrodt's chargeback data contained many other troubling examples—such as pharmacies purchasing Mallinckrodt oxycodone from as many as seven different distributors, downstream customers ordering only large amounts of oxycodone, distributors with rapidly escalating order volumes, and its continued sale of opioids to distributors it knew were shipping to downstream pharmacies and clinics that other distributors had previously cut off. In short, had Mallinckrodt looked at its own data, it would have seen the litany of red flags the DEA identified when it reviewed the sales activities of Mallinckrodt's wholesale distributor customers, and shut them down for posing an imminent danger to public health and safety. Mallinckrodt has claimed it lacked "visibility" of sales by its wholesale distributor customers to downstream customers such as pharmacies; however, the chargeback data proves otherwise.

1007. Mallinckrodt's own independent consultant conducted a review of its SOM program and confirmed numerous flaws. These flaws, including Mallinckrodt's exclusive reliance on a numerical formula to first identify peculiar orders, were so serious that he warned Mallinckrodt that it "would be unnecessarily exposing itself to potential liability." Mallinckrodt's consultant submitted his findings in a memo to Mallinckrodt dated November 2010, and was terminated by Mallinckrodt three months later, in January 2011.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

1008. Based on the evidence we have obtained, it is no surprise that in 2017, Mallinckrodt entered into an agreement with DEA and DOJ. According to the DEA, Mallinckrodt failed to:

- a. Conduct adequate due diligence of its customers;
- b. Detect and report to the DEA orders of unusual size and frequency;
- c. Use “chargeback” information from its distributors to evaluate suspicious orders; and
- d. Take effective action to prevent recurrences of diversion by downstream customers despite receiving concrete information of diversion by those customers.

1009. As part of this agreement, Mallinckrodt conceded that “at certain times [between January 1, 2008 and January 1, 2012], certain aspects of Mallinckrodt’s system to monitor and detect suspicious orders did not meet the standards outlined in letters” from the DEA in 2006 and 2007. As the team leader of compliance, Ms. Harper admitted during her deposition that she offered to resign since these egregious failures happened “under [her] watch,” but Mallinckrodt declined to accept her resignation.

1010. Mallinckrodt’s conduct is all the more egregious considering that for decades Mallinckrodt has been the leading manufacturer of methadone, which has been used to treat addiction since the 1960s. By the 1990s Mallinckrodt supplied, either directly or indirectly, 80 to 90 percent of all methadone used in drug treatment clinics in the U.S. Promoting its expertise gained from decades in the addiction treatment business, Mallinckrodt offered continuing education programs on the history and science of addiction, teaching that opioid drugs fit receptors in the brain like keys in locks, that opioids “hijack” the brain, and that as a result of the changes in brain structure and function, treatment (including medication like methadone) may be required for a lifetime. Mallinckrodt clearly knew the harm its products were capable of causing. It just didn’t care.

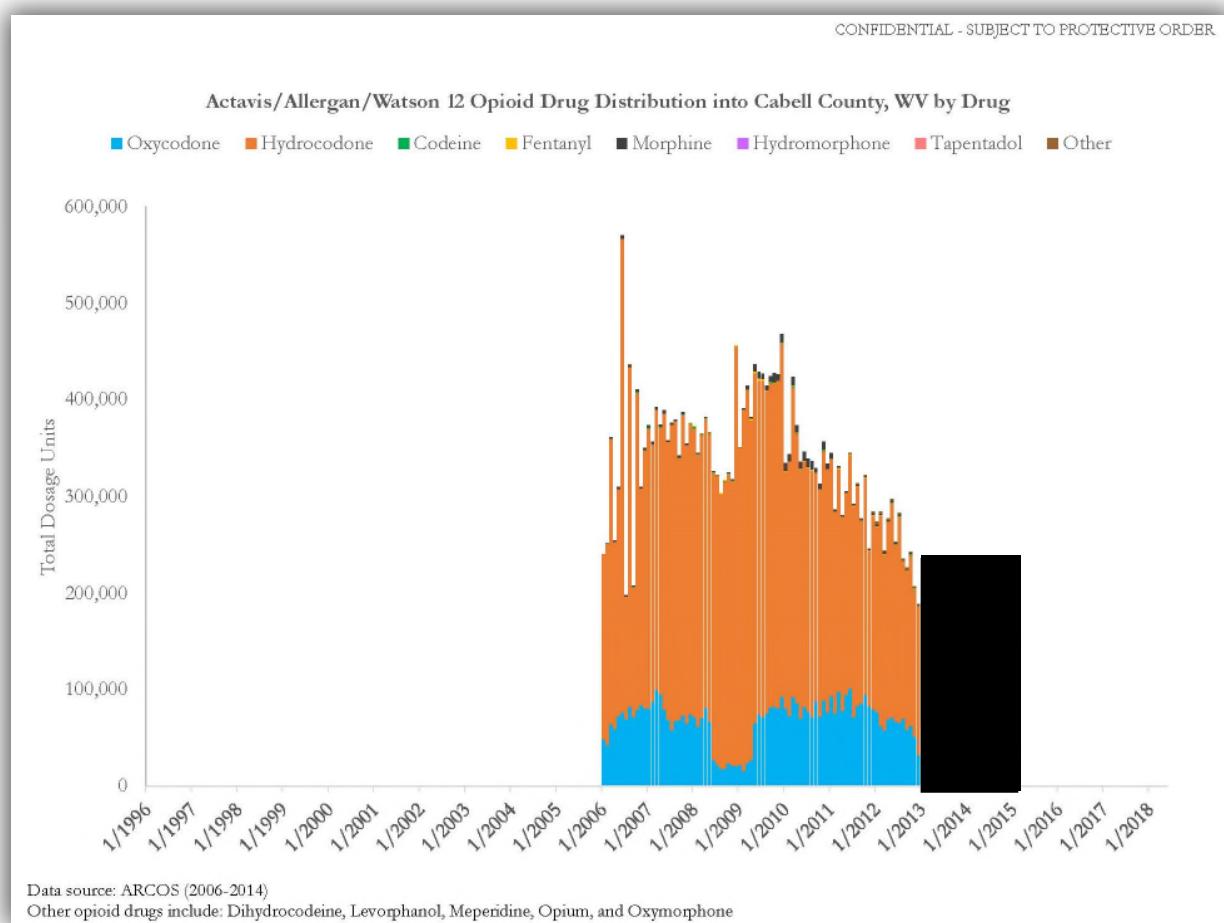
CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

1011. In 2017, the Department of Justice fined Mallinckrodt \$35 million for failure to report suspicious orders of controlled substances, including opioids, and for violating recordkeeping requirements. The government alleged that “Mallinckrodt failed to design and implement an effective system to detect and report ‘suspicious orders’ for controlled substances – orders that are unusual in their frequency, size, or other patterns . . . [and] Mallinckrodt supplied distributors, and the distributors then supplied various U.S. pharmacies and pain clinics, an increasingly excessive quantity of oxycodone pills without notifying DEA of these suspicious orders.”

xi. ACTAVIS

1012. Defendant Actavis breached its duties under federal and state law.

1013. As shown by the ARCos Data, Actavis sold an extraordinary amount of prescription opioids into Plaintiffs’ Community. Actavis’s excessive sales were made possible by, and are evidence of, Actavis’s failures to comply with its duties under the CSA.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

1014. Actavis failed to meet its suspicious order monitoring requirements, failed to stop shipment on suspicious orders, and failed to effectively prevent diversion in breach of its duties under state and federal law. These breaches contributed substantially to the public nuisance and harms alleged in the Plaintiffs' Community.

1015. Before the 2012 acquisition by Watson of Actavis, each maintained its own SOM system. Each conflicted with the guidance provided in the 2007 Rannazzisi letter. Until 2012, Actavis' SOM protocols were run by a single employee in the customer service group, Nancy Baran, who sent a 2009 email explaining that the process was inadequate to "prevent shipping excess product" because the report permitted a customer with a monthly usage threshold of 3000

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

units to order 2999 every day of the month and “[i]f we stopped to question and put on hold every one of the” flagged orders, “it would be crippling.” She concluded: “The intent of the DEA suspicious order report was designed to prevent excessive shipments of controlled products. In my opinion, it does a lousy job at even that.” Although Actavis produced documents reflecting approximately 7,000 orders flagged as suspicious, Baran testified that she believed the company determined that only one of the orders it flagged was ultimately reported to the DEA.

1016. During integration discussions in 2012, Watson’s SOM expert, Mary Woods, documented the Actavis system as “Not nearly as compliant as we could be” because it was a “[t]hreshold based report system” based on a six-month order average; noted Actavis has “no current SOP [standard operating procedures] on the current process”; commented that Actavis does “not investigate all, only some, since there is no SOP, they don’t investigate”; and concluded that the system was a “[d]efinite risk right now today, current system is not acceptable to Watson.”

1017. Actavis U.S. CEO Doug Boothe’s testimony confirms the inadequacy of Actavis’ SOM program: “I don’t think we had responsibility for, accountability for preventing diversion.” Boothe testified that, so long as the order was from a licensed pharmacy and within the SOM threshold, “we have no capability or responsibility or accountability So, once we ship an order to a wholesaler or ship a valid order to a distributor or another smaller wholesaler, our chain of custody is finished at that point.”

1018. On September 12, 2012, the DEA hosted a meeting with Actavis. Michael Clarke, Vice President of Ethics and Compliance, and Baran (among others), attended. During the meeting, the DEA excoriated Actavis for flooding the market with oxycodone. Clarke testified that the DEA treated Actavis like “street dealers” and treated it as if it “would just manufacture, put the product out on the street, and not have a care as to where it went.” The DEA summarized

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

this interaction in a memorandum produced at US-DEA-00000001. In addition to the memorandum, the document also includes more than 100 pages of material presented to Actavis at the meeting. In a follow-up meeting one month later, the DEA asked Actavis to reduce its oxycodone quota. CEO Boothe rejected the request.

1019. Actavis made efforts to improve its SOM system during 2012, including contracting with BuzzeoPDMA, a Cegedim Company (“Buzzeo”), and a new Buzzeo-based system was implemented in October 2012. But within three months, the combined Watson/Actavis company (renamed Actavis, Inc.) decided to use the previously existing Watson SOM system.

1020. Watson’s system was similarly deficient. Watson DEA Compliance Chief Officer Thomas Napoli criticized the system’s threshold-based approach as being inferior to a “total SOM model” that would “dynamically evaluate[] a variety of order characteristics.” Not only was Watson’s system threshold-based, it also affirmatively allowed customers to avoid violations of the thresholds by cancelling the order or reducing the order quantity – also violations of the 2007 Rannazzisi letter. Watson’s system also allowed orders to be shipped if a Watson employee (including someone from the sales team) provided mere email justification of the order.

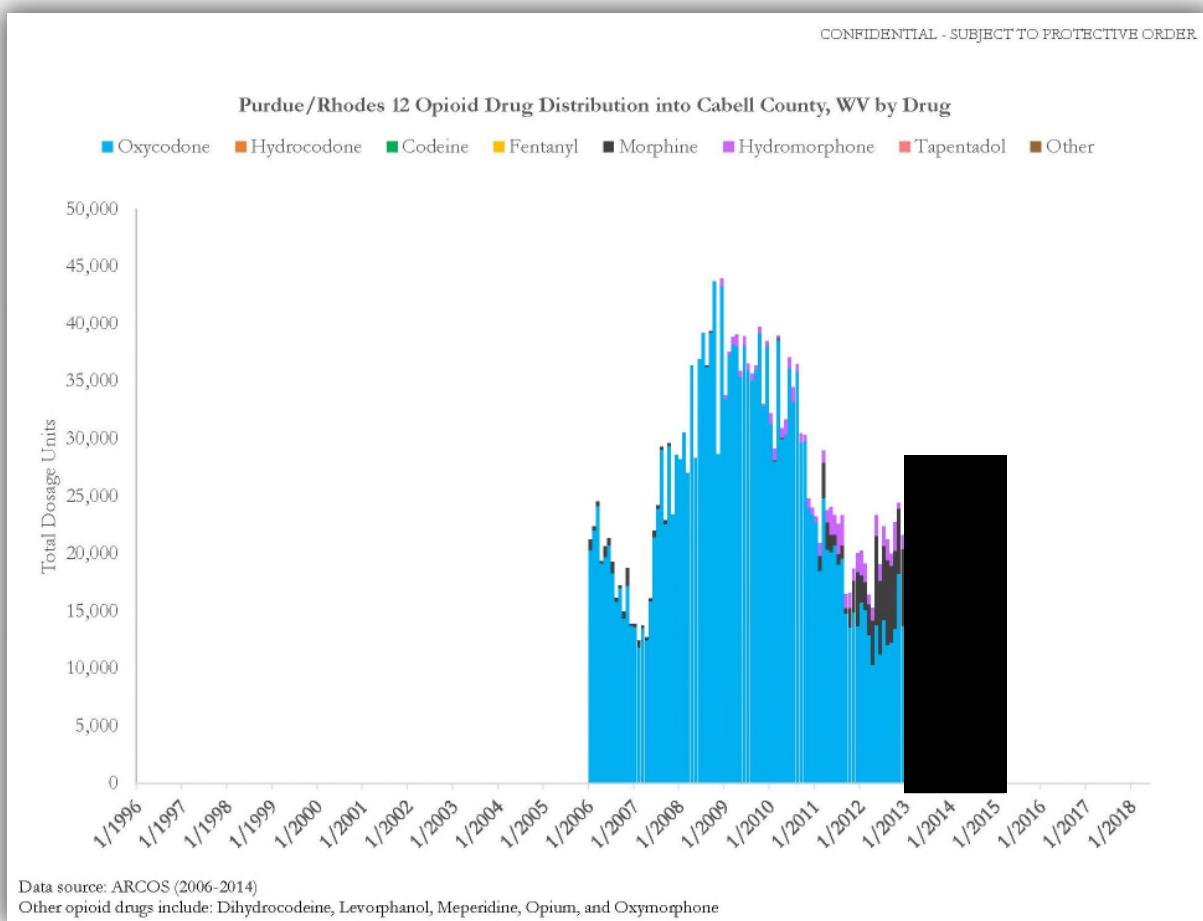
1021. Like pre-merger Actavis, pre-merger Watson hired Buzzeo to create a new system. The system, however, was never implemented due to the merger. Pre-merger Watson’s SOM system remained in place after the merger through 2016, when the sale of the generics business of the now-combined companies to Teva closed.

1022. In summary, Actavis maintained one of the largest market shares for prescription opioids nationally and in the CT1 jurisdictions and used SOM systems that employed improper threshold-based protocols, permitted orders to be modified to fit within the improper thresholds, and reported a grand total of approximately one suspicious order to the DEA.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER**xii. PURDUE**

1023. Defendant Purdue breached its duties under federal and state law.

1024. As shown by the ARCos Data, Purdue sold an extraordinary amount of prescription opioids into Plaintiffs' Community. Purdue's excessive sales were made possible by, and are evidence of, Actavis's failures to comply with its duties under the CSA.



1025. Purdue failed to meet its suspicious order monitoring requirements, failed to stop shipment on suspicious orders, and failed to effectively prevent diversion in breach of its duties under state and federal law. These breaches contributed substantially to the public nuisance and harms alleged in the Plaintiffs' Community.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

1026. Purdue failed to fulfill its responsibilities under state and federal law with respect to control of the supply chain of opioids. Purdue was required to set up a system to prevent diversion, including excessive volume and other suspicious orders. This includes reviewing Purdue's own data, relying on their observations of prescribers and pharmacies, and following up on reports or concerns of potential diversion. Purdue failed to do this.⁴²⁹ Part of Purdue's duties under the statute require that all suspicious orders must be reported to relevant enforcement authorities. Purdue was required to stop shipment of orders which were flagged as suspicious and only ship orders which were flagged as potentially suspicious if, after conducting due diligence, they can determine that the order is not likely to be diverted into illegal channels. Purdue failed to comply with its obligations under the statute.⁴³⁰ Despite these failures, Purdue's former Head of National Accounts, Steve Seid testified that Purdue had a "state of the art" and very "robust" SOM system. Purdue was so proud of its SOM system, that the Chair of the SOM Committee and member of General Counsel's office, Robin Abrams, gave a presentation to HDMA outlining the details of Purdue's SOM system so as to serve as an example to members in the industry.⁴³¹ Curtis Wright, likewise testified that abuse and diversion are inherent in opioids and at all points of the distribution chain there would be a "leak" and this is a function of volume.⁴³²

1027. Purdue's SOM system provides two streams of data providing total visibility down the chain –Purchasing Data and Prescribing Data. Purdue has specialized and detailed knowledge of the potential suspicious prescribing and dispensing of opioids through their regular visits to doctors' offices and pharmacies, and from their purchase of data from commercial sources, such

⁴²⁹ See generally, Deposition Testimony of Stephen See also PPLPC004000119319, Anda Order Email and PPLPC004000132946 Crowley SOM Email.

⁴³⁰ See generally, Deposition Testimony of Stephen and Collection of Seid Quick Approvals.

⁴³¹ PPLPC004000317962. Abram's SOM Presentation to HDMA

⁴³² See Deposition Testimony of Curtis Wright

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

as IMS. Their extensive boots-on-the-ground through their sales force, allows Purdue to observe the signs of suspicious prescribing and dispensing—lines of seemingly healthy patients, out-of-state license plates, and cash transactions, to name only a few.⁴³³ In addition, Purdue regularly mined data, including chargeback data, that allowed it to monitor the volume and type of prescribing of doctors, including sudden increases in prescribing and unusual high dose prescribing, which would have alerted Purdue, independent of their sales representatives, to suspicious prescribing. These information points gave Purdue insight into prescribing and dispensing conduct that enabled them to play a valuable role in the preventing diversion and fulfilling their obligations under the CSA.⁴³⁴

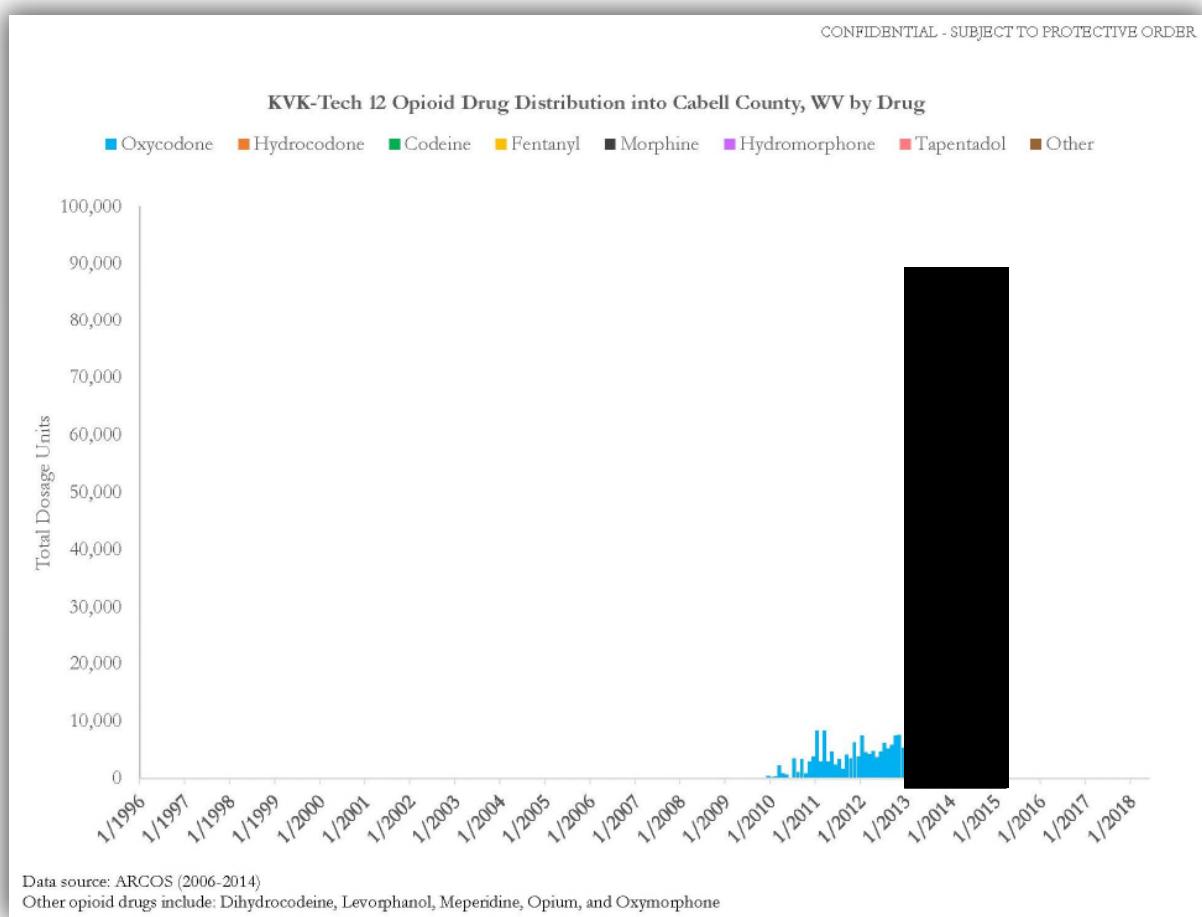
xiii. KVK TECH

1028. Defendant KVK Tech breached its duties under federal and state law.

1029. As shown by the AR COS Data, KV K Tech sold an extraordinary amount of prescription opioids into Plaintiffs' Community. KV K Tech's excessive sales were made possible by, and are evidence of, KV K Tech's failures to comply with its duties under the CSA.

⁴³³ See generally Deposition Testimony of Russell Gasdia describing the ADD program for prescriber reporting.

⁴³⁴ Purdue received this data as part of a Fee For Service ("FFS") Agreement that it had with its distributors. We have many examples of these agreements, one of which can be found at PPLP004397844. This is a FFS agreement between Purdue and Cardinal wherein the FFS details are specified.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

1030. KVK Tech failed to meet its suspicious order monitoring requirements, failed to stop shipment on suspicious orders, and failed to effectively prevent diversion in breach of its duties under state and federal law. These breaches contributed substantially to the public nuisance and harms alleged in the Plaintiffs' Community.

1031. Anthony Tabasso, KVK Tech CEO and President since 2013, admits that the "nation is in the midst of an opioid crisis" and that, as an opioid manufacture and seller, KVK has a duty to make sure "they don't get into the wrong hands, ... to look for signs of over prescription" and to "monitor" wholesalers and sales to pharmacies "as part of our charge from [the] (Drug Enforcement Agency) and as part of our internal procedures to monitor these things to try and

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

protect the public on two sides.” KVK admits its duty “to make sure that produced don’t get diverted.”⁴³⁵

1032. However, despite these admitted obligations, KVK Tech sold tens of thousands of dosage units of oxycodone into Cabell County in 2014 to a single pharmacy.

1033. The oxycodone opioids sold by KVK Tech in Cabell County were dispensed at a single pharmacy in Cabell County: A+ Pharmacy.

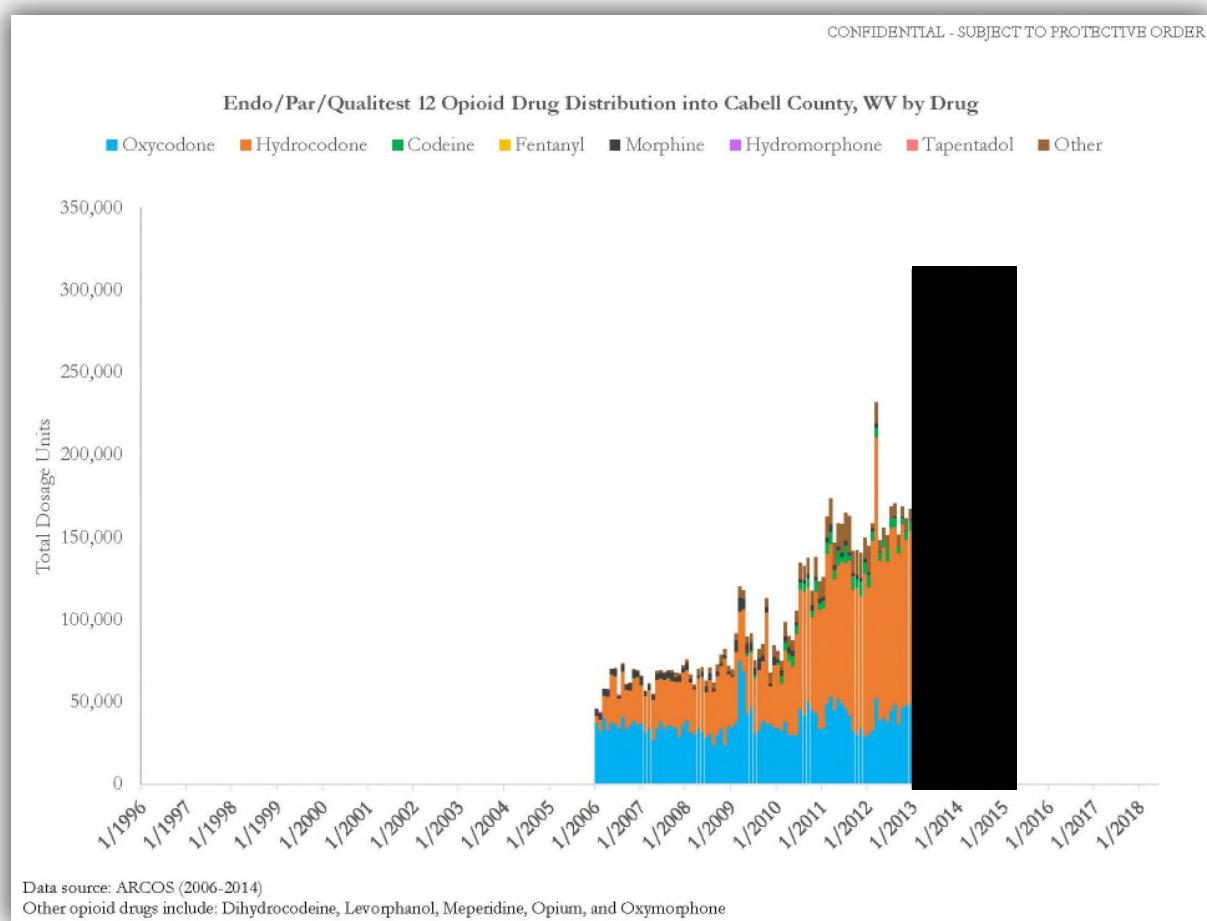
1034. The DOJ indicted Kofi Ohene Agyekum for drug distribution in the United States District Court for the Southern District of West Virginia (3:14-cr-00197) (September 10, 2014) arising out of his operation of A+ Pharmacy located in Cabell County. The pharmacy opened in November 2012 and distributed more than 90,000 doses of hydrocodone and more than 492,000 doses of oxycodone in a short 20 months before being shut down.

1035. KVK Tech breached its obligations under state and federal law

xiv. ENDO

1036. Defendant Endo breached its duties under federal and state law. As shown by the ARCos Data, Endo sold an extraordinary amount of prescription opioids into Plaintiffs’ Community. Endo’s excessive sales were made possible by, and are evidence of, Actavis’s failures to comply with its duties under the CSA.

⁴³⁵ Gabriel Perna, “Pharma CEO On Opioids, Medication Prices And Overregulation”, Chief Executive Group, Sept. 21, 2018, available at <https://chiefexecutive.net/pharma-opioids-medication-prices-overregulation/1/>

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

1037. Endo failed to meet its suspicious order monitoring requirements, failed to stop shipment on suspicious orders, and failed to effectively prevent diversion in breach of its duties under state and federal law. These breaches contributed substantially to the public nuisance and harms alleged in the Plaintiff's community.

1038. The Endo entities, including Qualitest and Par, had a duty to monitor for suspicious orders.⁴³⁶ Endo, however, never bothered to implement a robust SOM program (e.g., independent of commercial departments, using due diligence, using chargeback data, etc.) and never reported any orders to the DEA or blocked any orders as suspicious. UPS, a DEA registrant Endo used to

⁴³⁶ S. Macrides Tr. 62:8-64:4; ENDO-OPIOID_MDL-01500831 at 920; ENDO-CHI_LIT-00234542 at sec. 3.4.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

process and ship orders, likewise never reported or blocked any suspicious orders of Endo's opioids.⁴³⁷

1039. On the generic side, compliance and SOM personnel hired in 2012-2013 (after a DEA crack-down) identified a number of gaping holes in the Qualitest SOM process, including failure to monitor customers' customers and failure to use chargeback data to look for patterns.⁴³⁸ Qualitest recognized that SOM failures could lead to diversion with "heart-wrenching consequences" for communities.⁴³⁹ Similarly, Par had no SOM program as of 2010 and, when acquired by Endo in 2015, still had a program with glaring deficiencies (e.g., manual order review and only by sales employees, no real due diligence, an SOP that only discussed reporting "criminal" conduct to the DEA and made no mention of reporting "suspicious" orders).⁴⁴⁰ Although Endo/Par went through the motions to put a more "robust" SOM system in place on the generic side, it appears that was largely a paper process in which personnel were looking to check the boxes and clear orders, especially when it came to orders funneled through the major wholesalers. Very few orders were reported to the DEA and/or halted.

xv. JANSSEN

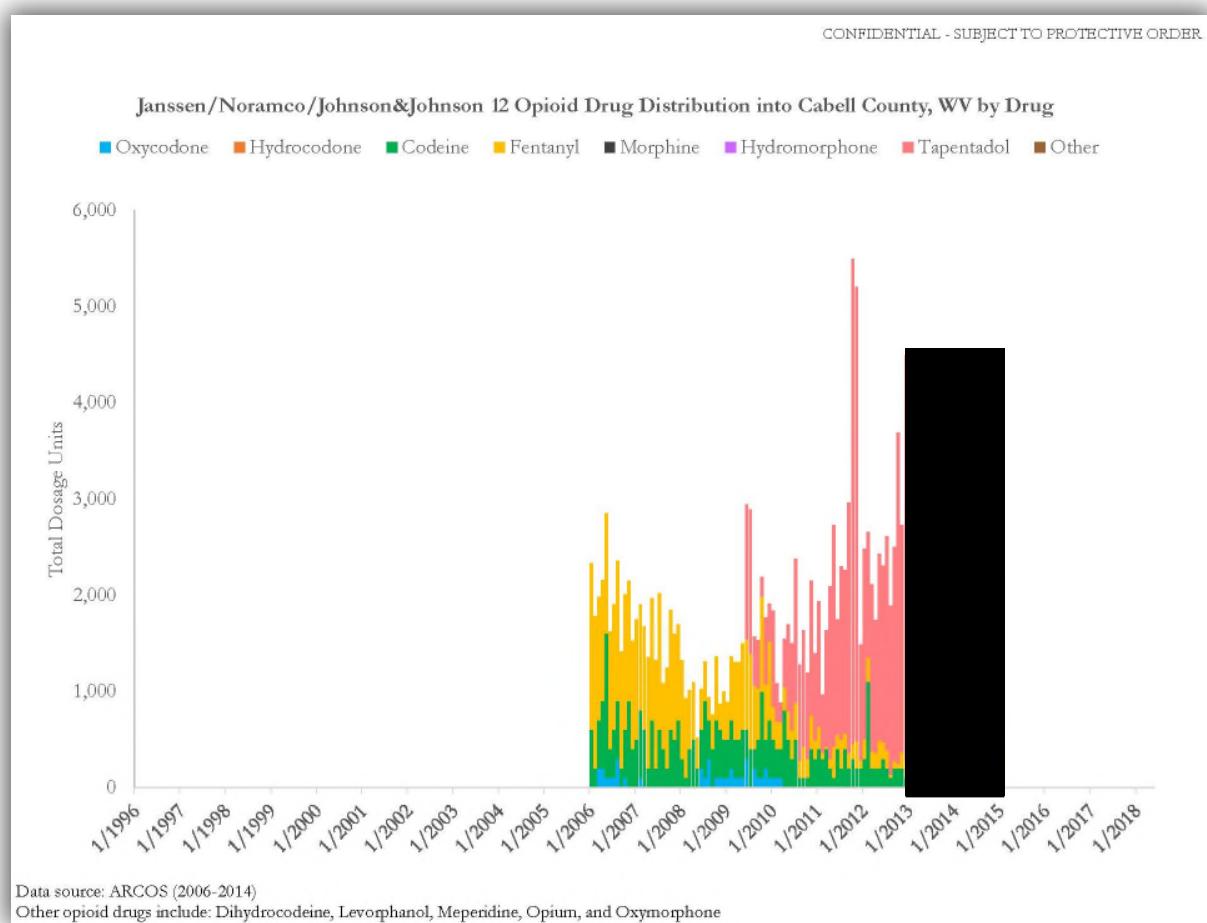
1040. Defendant Janssen breached its duties under federal and state law. As shown by the ARCOS Data, Janssen sold an extraordinary amount of prescription opioids into Plaintiffs' Community. Janssen's excessive sales were made possible by, and are evidence of, Janssen's failures to comply with its duties under the CSA.

⁴³⁷ L. Walker Tr. 65-68, 190, & 577-78.

⁴³⁸ PAR_OPIOID_MDL_0000363472; PAR_OPIOID_MDL_0000363469; PAR_OPIOID_MDL_0000216198; PAR_OPIOID_MDL_0000373334.

⁴³⁹ ABDCMDL00337067.

⁴⁴⁰ See also PAR_OPIOID_MDL_0001024072; PAR_OPIOID_MDL_000159366.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

1041. Since at least 2005, Janssen received chargeback data that would have provided it with visibility into the orders placed by its downstream customers.⁴⁴¹

1042. Starting from at least 2011, Janssen also purchased third-party data that, in combination with the chargeback information it received from wholesalers, Janssen used to spot high prescribers and to ensure that wholesalers were stocking targeted pharmacies with Janssen's opioids.⁴⁴² However, although Janssen regularly used this data to increase sales, it did not incorporate this information into its compliance program until as late as 2017.⁴⁴³

⁴⁴¹ JAN-MS-01117436

⁴⁴² JAN-MS-00454956

⁴⁴³ See Deposition of Michele Dempsey, at 98:15 – 99:16.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

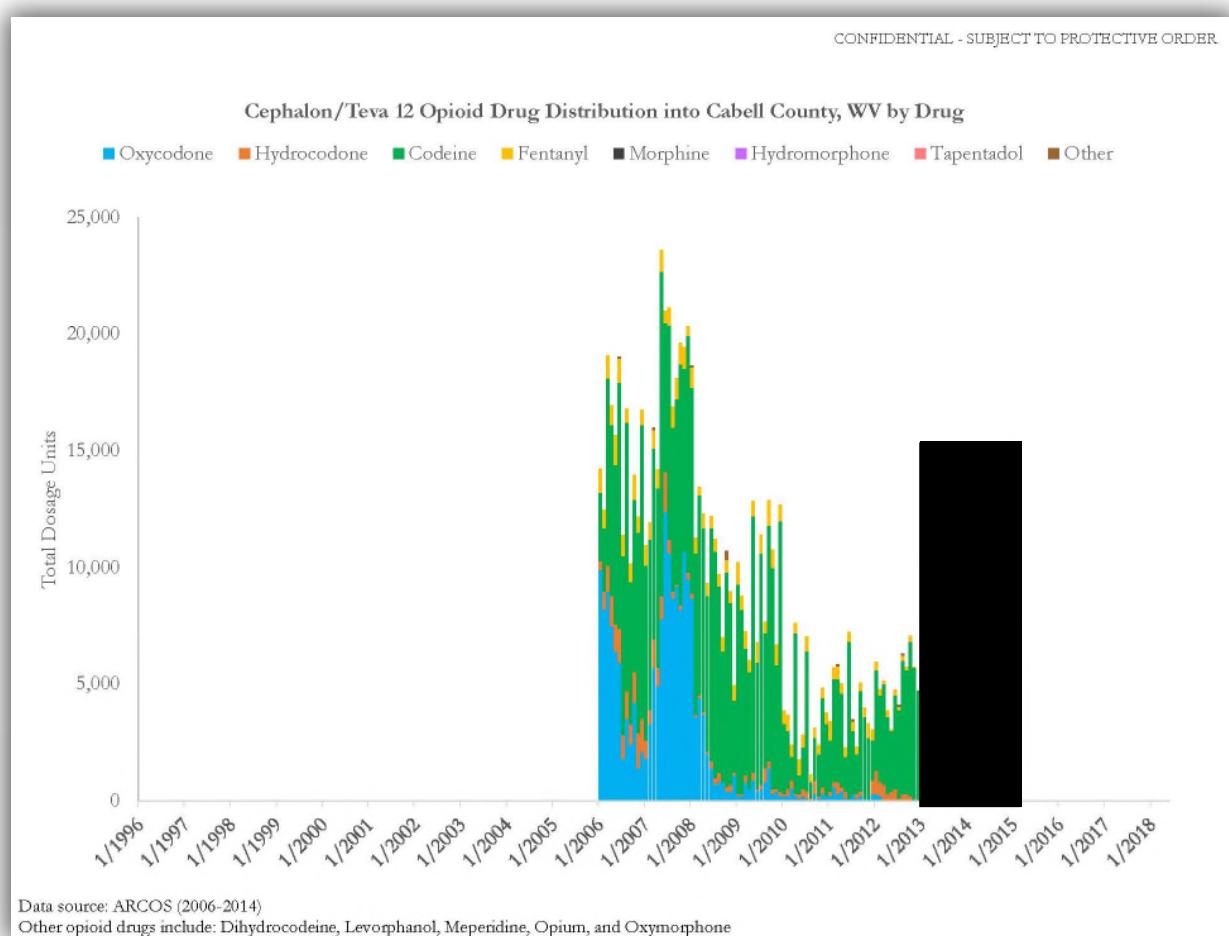
1043. A draft audit of Johnson & Johnson's Suspicious Order Monitoring programs dated January 8, 2018 concluded: "It appears that the JOM SOM has not reported an order for controlled substances as suspicious during its time in operation."⁴⁴⁴

1044. Janssen failed to meet its suspicious order monitoring requirements, failed to stop shipment on suspicious orders, and failed to effectively prevent diversion in breach of its duties under state and federal law. These breaches contributed substantially to the public nuisance and harms alleged in the Plaintiff's community.

xvi. CEPHALON

1045. Defendant Cephalon breached its duties under federal and state law. As shown by the ARCos Data, Cephalon sold an extraordinary amount of prescription opioids into Plaintiffs' Community. Cephalon's excessive sales were made possible by, and are evidence of, Cephalon's failures to comply with its duties under the CSA.

⁴⁴⁴ JAN-MS-05444748

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

1046. Cephalon failed to meet its suspicious order monitoring requirements, failed to stop shipment on suspicious orders, and failed to effectively prevent diversion in breach of its duties under state and federal law. These breaches contributed substantially to the public nuisance and harms alleged in the Plaintiffs' community

1047. Although Cephalon acknowledges that it was always under a regulatory obligation equal to that of the distributors to monitor and stop suspicious orders, it did not implement a SOM program until 2013.⁴⁴⁵

⁴⁴⁵ See, e.g., McGinn Dep. pp. 110-131; 136-137; 175-176; 386-389; Tomkiewicz Dep. pp. 174-203

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

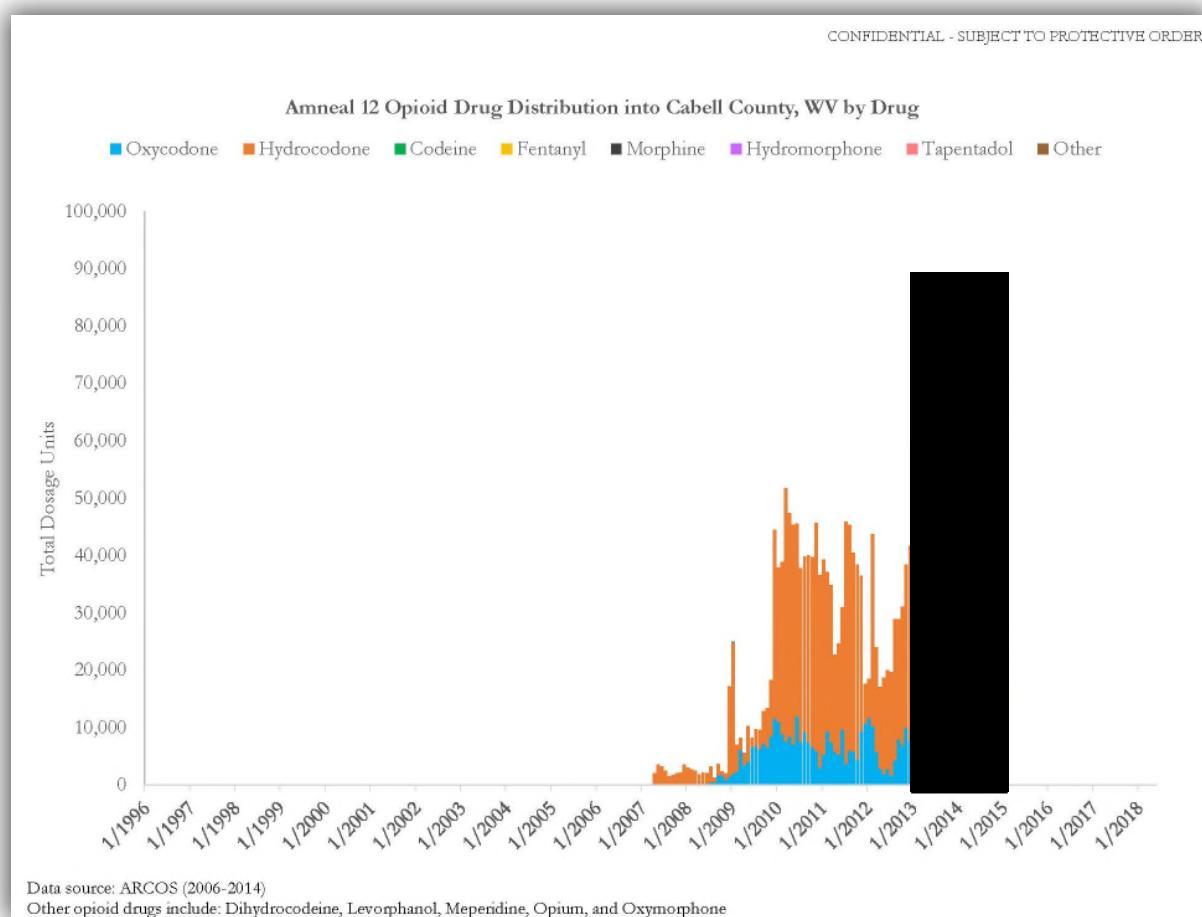
1048. In 2012, Cephalon hired Buzzeo to perform a review of its systems. The subsequent audit report described the existing SOMS systems as “rudimentary” and noted that no suspicious orders had ever been reported up to that point.

1049. Cephalon did not report a single suspicious order until 2013. From 2013 to 2016, it made only six suspicious order reports.

1050. Cephalon failed to meet its suspicious order monitoring requirements by failing to have proper policies and procedures in place that would have ensured its ability to stop shipment on suspicious orders. Because of this, it failed to effectively prevent diversion in breach of its duties under state and federal law. These breaches contributed substantially to the public nuisance and harms alleged in the Plaintiff’s community.

xvii. AMNEAL

1051. Defendant Amneal breached its duties under federal and state law. As shown by the ARCOS Data, Amneal sold an extraordinary amount of prescription opioids into Plaintiffs’ Community. Amneal’s excessive sales were made possible by, and are evidence of, Amneal’s failures to comply with its duties under the CSA.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

1052. Amneal failed to meet its suspicious order monitoring requirements, failed to stop shipment on suspicious orders, and failed to effectively prevent diversion in breach of its duties under state and federal law. These breaches contributed substantially to the public nuisance and harms alleged in the Plaintiff's community.

xviii. NATIONAL PHARMACIES

1053. Despite their legal obligations as registrants under the state and federal law, the National Pharmacies allowed widespread diversion to occur—and they did so knowingly.

1054. The National Defendants failed to adequately use data available to them to identify doctors who were writing suspicious numbers of prescriptions and/or prescriptions of suspicious

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

amounts of opioids, or to adequately use data available to them to do statistical analysis to prevent the filling of prescriptions that were illegally diverted or otherwise contributed to the opioid crisis.

1055. The National Pharmacies failed to analyze: (a) the number of opioid prescriptions filled by individual pharmacies relative to the population of the pharmacy's community; (b) the increase in opioid sales relative to past years; (c) the number of opioid prescriptions filled relative to other drugs; and (d) the increase in annual opioid sales relative to the increase in annual sales of other drugs.

1056. The National Pharmacies also failed to conduct adequate internal or external audits of their opioid sales to identify patterns regarding prescriptions that should not have been filled and to create policies accordingly, or if they conducted such audits, they failed to take any meaningful action as a result.

1057. The National Pharmacies were, or should have been, fully aware that the quantity of opioids being distributed and dispensed by them was untenable, and in many areas patently absurd; yet, they did not take meaningful action to investigate or to ensure that they were complying with their duties and obligations under the law with regard to controlled substances.

1058. Numerous regulatory actions reveal the National Pharmacies' systemic failures to fulfill their duties under state and federal law with respect to maintaining effective systems to prevent diversion and reporting and halting suspicious orders of controlled substances. The following is a merely a sampling:

a. CVS Regulatory Actions

1059. On October 13, 2010, CVS Pharmacy, Inc. entered into a Settlement Agreement with the United States and the DEA to resolve the criminal investigation of unlawful distribution and sales of pseudoephedrine ("PSE") by CVS/pharmacy stores in Southern California and Nevada

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

and a CVS/pharmacy distribution center in Southern California. The CVS Distribution Center in La Habra, California, was in a position to monitor and report excessive PSE sales to the DEA, but failed to do so, in violation of 21 U.S.C. Sec. 830(b) and 21 C.F.R. Sec. 1310.05(a)(1). CVS paid a penalty of \$75,000,000 and forfeited \$2.6 million in profits for a total payment of \$77.6 million.

1060. On March 28, 2013, CVS Pharmacy, Inc. and Oklahoma CVS Pharmacy L.L.C. entered into a Settlement Agreement with the United States and the DEA to resolve claims that CVS violated the CSA by : (1) filling prescriptions for certain prescribers whose DEA registration numbers were not current or valid; (2) entering and maintaining invalid DEA registration numbers on CVS dispensing records for certain prescriptions, which were at times provided to state prescription drug monitoring programs; and (3) entering and maintaining CVS dispensing records including prescription vial labels that identify a non-prescribing provider as the prescribing provider for certain prescriptions. CVS paid a fine of \$11,000,000.

1061. On September 2, 2014, CVS Pharmacy, Inc. entered into a Settlement Agreement with the United States and the DEA to resolve claims against CVS for filling (from April 1, 2012 to July 31, 2012) 153 prescriptions at eight (8) different pharmacies, written by the same physician, during a time period during which his Texas Department of Public Safety Controlled Substances registration was expired. CVS paid a \$1,912,500 fine.

1062. On May 12, 2015, CVS Health entered into a Settlement Agreement with the United States and the DEA. The Settlement resolved claims that CVS failed “to fulfill its corresponding responsibility to ensure that CVS dispensed controlled substances only pursuant to prescriptions issued for legitimate medical purposes by practitioners acting in the usual course of their professional practice, as required by 21 CF.R. §1306.64.” The Settlement also covered CVS’s “Florida Distribution Center[s] failure to maintain effective controls against the diversion of

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

controlled substances” and failure to timely detect and report suspicious orders of controlled substances. CVS's conduct complained of is set forth in the February 2, 2012 Orders to Show Cause and Immediate Suspension Orders issued to CVS stores 219 and 5195. CVS paid a fine of \$22,000,000.

1063. On August 7, 2015, CVS Health entered into a Settlement Agreement with the United States and the DEA. The Settlement resolved claims that between March 3, 2010 and August, 2015 CVS stores in Rhode Island (1) filled prescriptions with invalid prescriber DEA numbers (knew or should have known in violation of 21 U.S.C. § 842(a)(1) and 21 C.F.R. § 1306.04); (2) filled prescriptions for Schedule III controlled substances written by psychiatric nurse practitioners who were not authorized under state law or by terms of their DEA registration to issue such prescriptions, in violation of 21 U.S.C. § 842(a)(1) and 21 C.F.R. § 1306.03(a)(1); and (3) entering, creating, or maintaining CVS dispensing records in which the DEA registration numbers of non-prescribing practitioners, were substituted for the DEA registration numbers of prescribing practitioners, in violation of 21 U.S.C. § 842(a)(5) and 21 C.F.R. § 1306.24. CVS paid a \$450,000 fine.

1064. On December 31, 2015, the DEA issued a Letter of Admonition for violations in distributing HCPs at the CVS Indiana distribution center. This DEA finding was the result of the 2013 investigation. The DEA found that CVS violated the Controlled Substances Act because of a: “[f]ailure to design and maintain a system to detect suspicious and report suspicious orders for Schedule III-V Controlled Substances as required by Title 21 United States Code (USC) 821, Title 21 USC 823(e)(1), and Title 21 Code of Federal Regulations (CFR) 1301.74(b) in violation of Title 21 USC 842(a)(5) in that CVS failed to detect orders that should have been identified as suspicious for retail locations in Vincennes and Kokomo, Indiana.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

1065. On February 12, 2016, CVS Pharmacy, Inc. entered into a Settlement Agreement with the United States and the DEA. In the Settlement, CVS acknowledged that between 2008 and 2012, “certain CVS/pharmacy retail stores in Maryland did dispense certain controlled substances in a manner not fully consistent with their compliance obligations under the CSA....” CVS paid a fine of \$8,000,000.

1066. On June 30, 2016, CVS Pharmacy, Inc. entered into a Settlement Agreement with the United States and the DEA. The Settlement resolved claims that between 2011 and 2014 CVS pharmacies in Massachusetts had filled hundreds (523) of forged opioid prescriptions. CVS entered into a multi-year compliance agreement and paid a fine of \$3,500,000.

1067. On July 5, 2017, CVS Pharmacy, Inc. entered into a Settlement Agreement with the United States and the DEA as a result of a DEA investigation showing “an increase in the number of thefts and unexplained losses of Hydrocodone...” at numerous Eastern District of California CVS retail stores. The Settlement resolved claims for the following misconduct: 1) failure to “provide effective controls and procedures to guard against theft and diversion of controlled substances” (see 21 C.F.R. §1301.71(a)) and failure to notify the DEA of certain thefts or significant losses of controlled substances within one business day of the discovery (see 21 C.F.R. §1301.74(c)); 2) failure to maintain schedule 3-5 invoices (21 CFR §1304.04(a)); 3) failure to maintain Schedule 3-5 records separate from non-controlled substance records (21 CFR §1304.04 (h)(3)); 4) failure to conduct a Biennial Inventory on one specific day (21 CFR §1304.11(c)); 5) failure to maintain complete and accurate records (21 CFR §1304.21(a)); 6) failure to record the date of acquisition of controlled substances (21 CFR §1304.22(c), 1304.22(a)(2)(iv)); 7) failure to record the amount received on Schedule 3-5 invoices (21 CFR §1304.22(c)); 8) failure to record the amount received and the date received on DEA 222 forms

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

(21 CFR §1305.13(e)); 9) failure to maintain DEA-222 forms (21 CFR §1305. 17(a)); and 10) failure to maintain DEA-222 forms separate from other records (21 CFR §1305. 17(c)). CVS admitted that between April 30, 2011 and April 30, 2013 the retail stores violated their recordkeeping obligations but it denied that the recordkeeping obligations caused any diversion. CVS paid a fine of \$5,000,000.

b. Walgreens Regulatory Actions

1068. In May 2006, the DEA sent Walgreens a Letter of Admonition citing Walgreens for recordkeeping inadequacies and security deficiencies at its Perrysburg Distribution Center. Specifically, the DEA found that the “formulation utilized by the firm for reporting suspicious ordering of controlled substances was insufficient.”⁴⁴⁶

1069. In 2008, Walgreens entered into a Corporate Integrity Agreement related to its non-compliant dispensing practices

1070. The allegations in the OTSC and ISO were exacerbated by the fact that over a year earlier, on April 7, 2011, Walgreens had entered into a prior Settlement Agreement with DEA regarding allegations of non-compliance with the Controlled Substance Act wherein Walgreens had agreed to “maintain a compliance program to detect and prevent diversion of controlled substances.”⁴⁴⁷

1071. In April 2012, the DEA served a Subpoena to one of Walgreens’s Schedule 2 controlled substance distribution centers, the Jupiter Distribution Center, requesting, among other things, all controlled substance SOPs, communications about controlled substances, and customer

⁴⁴⁶ WAGMDL00709510.

⁴⁴⁷ See Walgreens 2013 MOA (WAGMDL00490963-WAGMDL00490978; WAGMDL00387975-WAGMDL00387982; WAGMDL00387653-WAGMDL00387974) at WAGMDL00387975.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

due diligence files for 14 Walgreens stores, and also served a Warrant of Inspection on the Jupiter Distribution Center, authorizing seizure, among other things, all records related to distribution of controlled substances.⁴⁴⁸

1072. After reviewing the materials provided by Walgreens in response to the April 2012 subpoenas, on September 13, 2012, the DEA issued an Order to Show Cause (OTCS) and Immediate Suspension of Registration (ISO) to Walgreens on the basis that the Jupiter Distribution Center constituted “an imminent danger to the public health and safety” and ordered that Jupiter controlled substance vault be sealed.⁴⁴⁹ The DEA alleged that Walgreens’s Jupiter DC failed to comply with DEA regulations that required it to report to the DEA suspicious drug orders that Walgreens received from its retail pharmacies. Further, the DEA alleged that Walgreens’s failure to sufficiently report suspicious orders was a systemic practice that resulted in at least tens of thousands of violations and allowed Walgreens’ retail pharmacies to order and receive at least three times the Florida average for drugs such as oxycodone.

1073. In February 2013, the DEA issued similar Subpoenas and Warrant of Inspection on the Perrysburg Distribution Center.⁴⁵⁰ Walgreens employees made plans in preparation for the Perrysburg DC being “shut down” by the DEA, like the Jupiter DC.⁴⁵¹ Within weeks of receiving the six subpoenas and warrant, Walgreens decided to “discontinue distribution of controlled

⁴⁴⁸ WAGMDL00777158; CAH_MDL2804_01431074.

⁴⁴⁹ See Settlement and Memorandum of Agreement between the Department of Justice, DEA, and Walgreens Co., with appendices (collectively, “Walgreens 2013 MOA”) (WAGMDL00490963-WAGMDL00490978; WAGMDL00387975-WAGMDL00387982; WAGMDL00387653-WAGMDL00387974) at WAGMDL00387654 (Letter from Michele Leonhart to Walgreen Company, *Order to Show Cause and Immediate Suspension of Registration* (Sept. 13, 2012), [“Jupiter Show Cause Order”]).

⁴⁵⁰ WAGMDL00493697; WAGMDL00493694.

⁴⁵¹ WAGMDL00477975; WAGMDL00358471.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

substances from the Perrysburg facility” in order to “eliminate any immediate need for further DEA administrative action” regarding the Perrysburg facility.⁴⁵²

1074. On June 11, 2013 Walgreens entered into a Settlement and Memorandum of Agreement (“MOA”) with the DEA to resolve outstanding allegations involving the Walgreens Distribution Centers and pending actions concerning six Walgreens retail pharmacies located in Florida. Walgreens agreed to pay \$80 million in civil penalties, the largest settlement in DEA history at that time, to resolve the DEA’s claims that Walgreens negligently allowed controlled substances, including oxycodone and other prescription painkillers, to be diverted into the black market.⁴⁵³ In addition to the \$80 million civil penalty, Walgreens agreed to surrender its Jupiter DC’s registration to distribute or dispense controlled substances listed in Schedules II – V for two years from issuance of the Jupiter ISO, ending in 2014. As part of the MOA, Walgreens admitted that Walgreens’s “suspicious order reporting for distribution to certain pharmacies did not meet the standards identified by DEA in three letters from DEA's Deputy Assistant Administrator, Office of Diversion Control, sent to every registered manufacturer and distributor, including Walgreens, on September 27, 2006, February 7, 2007 and December 27, 2007.”

c. Rite Aid Regulatory Actions

1075. On January 11, 2009, Rite Aid entered into an agreement to pay \$5 Million in civil penalties for CSA violations and to enter into a Compliance Plan to ensure compliance with all requirements of the CSA and application DEA regulations and prevent diversion of controlled

⁴⁵² WAGMDL00674280.

⁴⁵³ See Walgreens 2013 MOA (WAGMDL00490963-WAGMDL00490978; WAGMDL00387975-WAGMDL00387982; WAGMDL00387653-WAGMDL00387974).

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

substances. This action was based on system violations of Rite Aid's obligation to prevent diversion across 53 Rite Aid pharmacy locations.

1076. On March 9, 2017, Rite Aid entered into an agreement to pay \$834,200 in civil fines for CSA violations.

G. Defendants' Violations in Other Jurisdictions Further Exacerbated the Flood of Opioids into the City of Huntington and Cabell County.

1077. As the demand for prescription opioids grew, fueled by their potency and purity, interstate commerce flourished: opioids moved from areas of high supply to areas of high demand, traveling across state lines in a variety of ways.

1078. First, prescriptions written in one state may, under some circumstances, be filled in a different state. But even more significantly, individuals transported opioids from one jurisdiction specifically to sell them.

1079. When authorities in states such as Ohio, Kentucky and West Virginia cracked down on opioid suppliers, out-of-state suppliers filled the gaps. Florida in particular assumed a prominent role, as its lack of regulatory oversight created a fertile ground for pill mills. Residents of the Tri-States would simply drive to Florida, stock up on pills from a pill mill, and transport them back to home to sell. The practice became so common that authorities dubbed these individuals "prescription tourists."

1080. The route from Florida and Georgia to the Tri-State area of Kentucky, Ohio, and West Virginia was so well traveled that it became known as the Blue Highway, a reference to the color of the 30mg roxicodone pills manufactured by Mallinckrodt. Eventually, as police began to stop vehicles with certain out-of-state tags cruising north on I-75, the prescription tourists adapted. They rented cars just over the Georgia state line to avoid the telltale out-of-state tag. If they were visiting multiple pill mills on one trip, they would stop at FedEx between clinics to mail the pills

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

home and avoid the risk of being caught with multiple prescriptions if pulled over. Or they avoided the roads altogether: Allegiant Air, which offered several flights between Appalachia and Florida, was so popular with drug couriers that it was nicknamed the “Oxy Express.”

1081. While the I-75 corridor was well utilized, prescription tourists also came from other states. The director of the Georgia drugs and narcotics agency observed that visitors to Georgia pill mills come from as far away as Arizona and Nebraska.

1082. Similar pipelines developed in other regions of the country. For example, the I-95 corridor was another transport route for prescription pills. As the director of the Maine Drug Enforcement Agency explained, the oxycodone in Maine was coming up extensively from Florida, Georgia and California. And, according to the FBI, Michigan plays an important role in the opioid epidemic in other states; opioids prescribed in Michigan are often trafficked down to West Virginia, Ohio, and Kentucky.

1083. Along the West Coast, over a million pills were transported from the Lake Medical pain clinic in Los Angeles and cooperating pharmacies to the city of Everett, Washington. Couriers drove up I-5 through California and Oregon, or flew from Los Angeles to Seattle. The Everett-based dealer who received the pills from southern California wore a diamond necklace in the shape of the West Coast states with a trail of green gemstones—the color of 80-milligram OxyContin—connecting Los Angeles and Washington state.

1084. Abundant evidence, thus, establishes that prescription opioids migrated between cities, counties, and states, including into the Tri-States from places like Florida. As a result, prescription data from any particular jurisdiction does not capture the full scope of the misuse, oversupply and diversion problem in that specific area. As the criminal prosecutions referenced above show, if prescription opioid pills were hard to get in one area, they migrated from another.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

The manufacturers, distributors, and dispensers were fully aware of this phenomenon and profited from it.

H. Defendants Delayed a Response to the Opioid Crisis by Pretending to Cooperate with Law Enforcement

1085. When a registrant manufacturer, distributor, or dispenser of does not report or stop suspicious orders, prescriptions for controlled substances may be written and dispensed to individuals who abuse them or who sell them to others to abuse. This, in turn, fuels and expands the illegal market and results in opioid-related overdoses. Without reporting by those involved in the supply chain, law enforcement may be delayed in taking action – or may not know to take action at all.

1086. After being caught for failing to comply with particular obligations at particular facilities, Distributor Defendants made broad promises to change their ways and insisted that they sought to be good corporate citizens. As part of McKesson’s 2008 Settlement with the DEA, McKesson claimed to have “taken steps to prevent such conduct from occurring in the future,” including specific measures delineated in a “Compliance Addendum” to the Settlement. Yet, in 2017, McKesson paid \$150 million to resolve an investigation by the U.S. DOJ for again failing to report suspicious orders of certain drugs, including opioids. Even though McKesson had been sanctioned in 2008 for failure to comply with its legal obligations regarding controlling diversion and reporting suspicious orders, and even though McKesson had specifically agreed in 2008 that it would no longer violate those obligations, McKesson continued to violate the laws in contrast to its written agreement not to do so.

1087. More generally, the Distributor Defendants publicly portrayed themselves as committed to working with law enforcement, opioid manufacturers, and others to prevent diversion of these dangerous drugs. For example, Defendant Cardinal claims that: “We challenge

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

ourselves to best utilize our assets, expertise and influence to make our communities stronger and our world more sustainable, while governing our activities as a good corporate citizen in compliance with all regulatory requirements and with a belief that doing ‘the right thing’ serves everyone.” Defendant Cardinal likewise claims to “lead [its] industry in anti-diversion strategies to help prevent opioids from being diverted for misuse or abuse.” Along the same lines, it claims to “maintain a sophisticated, state-of-the-art program to identify, block and report to regulators those orders of prescription-controlled medications that do not meet [its] strict criteria.” Defendant Cardinal also promotes funding it provides for “Generation Rx,” which funds grants related to prescription drug misuse. A Cardinal executive recently claimed that Cardinal uses “advanced analytics” to monitor its supply chain; Cardinal assured the public it was being “as effective and efficient as possible in constantly monitoring, identifying, and eliminating any outside criminal activity.”

1088. Along the same lines, Defendant McKesson publicly claims that its “customized analytics solutions track pharmaceutical product storage, handling and dispensing in real time at every step of the supply chain process,” creating the impression that McKesson uses this tracking to help prevent diversion. Defendant McKesson has also publicly stated that it has a “best-in-class controlled substance monitoring program to help identify suspicious orders,” and claimed it is “deeply passionate about curbing the opioid epidemic in our country.”

1089. Defendant AmerisourceBergen, too, has taken the public position that it is “work[ing] diligently to combat diversion and [is] working closely with regulatory agencies and other partners in pharmaceutical and healthcare delivery to help find solutions that will support appropriate access while limiting misuse of controlled substances.” A company spokeswoman also

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

provided assurance that: “At AmerisourceBergen, we are committed to the safe and efficient delivery of controlled substances to meet the medical needs of patients.”

1090. Moreover, in furtherance of their effort to affirmatively conceal their conduct and avoid detection, the Defendants, through their trade associations, HDMA and NACDS, filed an *amicus* brief in *Masters Pharmaceuticals*, which made the following statements:⁴⁵⁴

“HDMA and NACDS members not only have statutory and regulatory responsibilities to guard against diversion of controlled prescription drugs, but undertake such efforts as responsible members of society.”

“Distributors take seriously their duty to report suspicious orders, utilizing both computer algorithms and human review to detect suspicious orders based on the generalized information that *is* available to them in the ordering process.”

1091. Through the above statements made on their behalf by their trade associations, and other similar statements assuring their continued compliance with their legal obligations, the Defendants not only acknowledged that they understood their obligations under the law, but they further affirmed that their conduct was in compliance with those obligations. Defendant Mallinckrodt similarly claims to be “committed . . . to fighting opioid misuse and abuse,” and further asserts that: “In key areas, our initiatives go beyond what is required by law. We address diversion and abuse through a multidimensional approach that includes educational efforts, monitoring for suspicious orders of controlled substances, . . .”

1092. Other Manufacturer Defendants also misrepresented their compliance with their legal duties and their cooperation with law enforcement. Purdue serves as a hallmark example of such wrongful conduct. Purdue deceptively and unfairly failed to report to authorities illicit or suspicious prescribing of its opioids, even as it has publicly and repeatedly touted its “constructive

⁴⁵⁴ Brief for HDMA and NACDS, *Masters Pharms., Inc. v. U.S. Drug Enf't Admin.*, Case No 15-1335, 2016 WL 1321983, (D.C. Cir. April 4, 2016) at *3-4, *25.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

role in the fight against opioid abuse,” including its commitment to ADF opioids and its “strong record of coordination with law enforcement.”⁴⁵⁵

1093. As described above, at the heart of Purdue’s public outreach is the claim that it works hand-in-glove with law enforcement and government agencies to combat opioid abuse and diversion.

1094. Public statements by the Defendants and their associates created the false and misleading impression to regulators, prescribers, and the public that the Defendants rigorously carried out their legal duties, including their duty to report suspicious orders and exercise due diligence to prevent diversion of these dangerous drugs, and further created the false impression that these Defendants also worked voluntarily to prevent diversion as a matter of corporate responsibility to the communities their business practices would necessarily impact.

I. Defendants Worked Together to Sustain their Market and Boost their Profits

1. Defendants Worked Together to Inflate Quotas

1095. Finding it impossible to legally achieve their ever-increasing sales ambitions within the confines of their quotas, Defendants engaged in the common purpose of increasing the supply of opioids and fraudulently increasing the quotas that governed the manufacture and distribution of their prescription opioids.

1096. The CSA requires manufacturers and distributors of prescription opioids to: (a) limit sales within a quota set by the DEA for the overall production of opioids; (b) register to manufacture or distribute opioids; (c) maintain effective controls against diversion of the controlled substances that they manufacture or distribute; and (d) design and operate a system to

⁴⁵⁵ Purdue, *Setting The Record Straight On OxyContin’s FDA-Approved Label* (May 5, 2016), <http://www.purduepharma.com/news-media/get-the-facts/setting-the-record-straight-on-oxycontin-s-fda-approved-label/>; Purdue, *Setting The Record Straight On Our Anti-Diversion Programs*, (July 11, 2016) <http://www.purduepharma.com/news-media/get-the-facts/setting-the-record-straight-on-our-anti-diversion-programs/>.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

identify suspicious orders of controlled substances, halt such unlawful sales, and report them to the DEA.

1097. Central to the closed system created by the CSA was the directive that the DEA determine quotas of each basic class of Schedule I and II controlled substances each year. The quota system was intended to reduce or eliminate diversion from “legitimate channels of trade” by controlling the “quantities of the basic ingredients needed for the manufacture of [controlled substances], and the requirement of order forms for all transfers of these drugs.” When evaluating production quotas, the DEA was instructed to consider the following information:

Information provided by the Department of Health and Human Services;

- a. Total net disposal of the basic class [of each drug] by all manufacturers;
- b. Trends in the national rate of disposal of the basic class [of drug];
- c. An applicant’s production cycle and current inventory position;
- d. Total actual or estimated inventories of the class [of drug] and of all substances manufactured from the class and trends in inventory accumulation; and
- e. Other factors such as: changes in the currently accepted medical use of substances manufactured for a basic class; the economic and physical availability of raw materials; yield and sustainability issues; potential disruptions to production; and unforeseen emergencies.

1098. It is unlawful to manufacture a controlled substance in Schedule II, like prescription opioids, in excess of a quota assigned to that class of controlled substances by the DEA.

1099. Distributor Defendants had close financial relationships with both Manufacturing Defendants and customers, for whom they provide a broad range of value-added services that render them uniquely positioned to obtain information and control against diversion. These services often otherwise would not be provided by manufacturers to their dispensing customers and would be difficult and costly for the dispenser to reproduce. For example, “[w]holesalers have

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

sophisticated ordering systems that allow customers to electronically order and confirm their purchases, as well as to confirm the availability and prices of wholesalers' stock." *Fed. Trade Comm'n v. Cardinal Health, Inc.*, 12 F. Supp. 2d 34, 41 (D.D.C. 1998). Through their generic source programs, wholesalers are also able "to combine the purchase volumes of customers and negotiate the cost of goods with manufacturers." Wholesalers typically also offer marketing programs, patient services, and other software to assist their dispensing customers.

1100. Distributor Defendants had financial incentives from the Manufacturer Defendants to distribute higher volumes, and thus to refrain from reporting or declining to fill suspicious orders. Wholesale drug distributors acquire pharmaceuticals, including opioids, from manufacturers at an established wholesale acquisition cost. Discounts and rebates from this cost may be offered by manufacturers based on market share and volume. As a result, higher volumes may decrease the cost per pill to distributors. Decreased cost per pill in turn, allows wholesale distributors to offer more competitive prices, or alternatively, pocket the difference as additional profit. Either way, the increased sales volumes result in increased profits.

1101. The Manufacturer Defendants engaged in the practice of paying rebates and/or chargebacks to the Distributor Defendants for sales of prescription opioids as a way to help them boost sales. The *Washington Post* has described the practice as industry-wide, and the HDA includes a "Contracts and Chargebacks Working Group," suggesting a standard practice. Further, in a recent settlement with the DEA, Mallinckrodt, a prescription opioid manufacturer, acknowledged that "[a]s part of their business model Mallinckrodt collects transaction information, referred to as chargeback data, from their direct customers (distributors)." The transaction information contains data relating to the direct customer sales of controlled substances to 'downstream' registrants," meaning pharmacies or other dispensaries, such as hospitals.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

Manufacturer Defendants buy data from pharmacies as well. This exchange of information, upon information, and belief, would have opened channels providing for the exchange of information revealing suspicious orders as well.

1102. The contractual relationships among the Defendants also include vault security programs. Defendants are required to maintain certain security protocols and storage facilities for the manufacture and distribution of their opiates. The manufacturers negotiated agreements whereby the Manufacturer Defendants installed security vaults for the Distributor Defendants in exchange for agreements to maintain minimum sales performance thresholds. These agreements were used by the Defendants as a tool to violate their reporting and diversion duties in order to reach the required sales requirements.

2. Defendants Worked Together to Shape State and Federal Policy

1103. Defendants worked together to achieve their common purpose through trade or other organizations, such as the Pain Care Forum (“PCF”) and the HDA.

1104. The PCF has been described as a coalition of drug makers, trade groups and dozens of non-profit organizations supported by industry funding, including the Front Groups described in this Complaint. The PCF recently became a national news story when it was discovered that lobbyists for members of the PCF quietly shaped federal and state policies regarding the use of prescription opioids for more than a decade.

1105. The Center for Public Integrity and The Associated Press obtained “internal documents shed[ding] new light on how drug makers and their allies shaped the national response to the ongoing wave of prescription opioid abuse.”⁴⁵⁶ Specifically, PCF members spent over \$740

⁴⁵⁶ Matthew Perrone, *Pro-Painkiller echo chamber shaped policy amid drug epidemic*, The Center for Public Integrity, <https://www.publicintegrity.org/2016/09/19/20201/pro-painkiller-echochamber-shaped-policy-amid-drug-epidemic>. (Last Updated Dec. 15, 2016, 9:09 AM) (emphasis added).

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

million lobbying in the nation's capital and in all 50 statehouses on an array of issues, including opioid-related measures.⁴⁵⁷

1106. The Defendants who stood to profit from expanded prescription opioid use are members of and/or participants in the PCF. In 2012, membership and participating organizations included Actavis. Each of the Manufacturer Defendants worked together through the PCF. But, the Manufacturer Defendants were not alone. The Distributor Defendants actively participated, and continue to participate in the PCF, at a minimum, through their trade organization, the HDA.⁴⁵⁸ The Distributor Defendants participated directly in the PCF as well.

1107. Additionally, the HDA led to the formation of interpersonal relationships and an organization among the Defendants. Although the entire HDA membership directory is private, the HDA website confirms that each of the Distributor Defendants and the Manufacturer Defendants including Actavis and Mallinckrodt were members of the HDA. Additionally, the HDA and each of the Distributor Defendants, eagerly sought the active membership and participation of the Manufacturer Defendants by advocating for the many benefits of members, including "strengthen[ing] . . . alliances."⁴⁵⁹

1108. Beyond strengthening alliances, the benefits of HDA membership included the ability to, among other things, "network one on one with manufacturer executives at HDA's members-only Business and Leadership Conference," "networking with HDA wholesale distributor members," "opportunities to host and sponsor HDA Board of Directors events,"

⁴⁵⁷ *Id.*

⁴⁵⁸ *Id.*; The Executive Committee of the HDA (formerly the HDMA) currently includes the Chief Executive Officer, Pharmaceutical Segment for Cardinal Health, Inc., the Group President, Pharmaceutical Distribution and Strategic Global Source for AmerisourceBergen Corporation, and the President, U.S. Pharmaceutical for McKesson Corporation. *Executive Committee*, Healthcare Distribution Alliance,

<https://www.healthcaredistribution.org/about/executive-committee> (last accessed Apr. 25, 2018).

⁴⁵⁹ *Manufacturer Membership*, Healthcare Distribution Alliance,

<https://healthcaredistribution.org/about/membership/manufacturer> (last accessed Apr. 25, 2018).

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

“participate on HDA committees, task forces and working groups with peers and trading partners,” and “make connections.”⁴⁶⁰ Clearly, the HDA and the Defendants believed that membership in the HDA was an opportunity to create interpersonal and ongoing organizational relationships and “alliances” between the Manufacturer Defendants and the Distributor Defendants.

1109. The application for manufacturer membership in the HDA further indicates the level of connection among the Defendants and the level of insight that they had into each other’s businesses.⁴⁶¹ For example, the manufacturer membership application must be signed by a “senior company executive,” and it requests that the manufacturer applicant identify a key contact and any additional contacts from within its company.

1110. The HDA application also requests that the manufacturer identify its current distribution information, including the facility name and contact information. Manufacturer members were also asked to identify their “most recent year end net sales” through wholesale distributors, including the Distributor Defendants AmerisourceBergen, Cardinal Health, and McKesson and their subsidiaries.

1111. The closed meetings of the HDA’s councils, committees, task forces and working groups provided the Manufacturer and Distributor Defendants with the opportunity to work closely together, confidentially, to develop and further the common purpose and interests of the enterprise.

1112. The HDA also offers a multitude of conferences, including annual business and leadership conferences. The HDA and the Distributor Defendants advertise these conferences to the Manufacturer Defendants as an opportunity to “bring together high-level executives, thought

⁴⁶⁰ *Id.*

⁴⁶¹ *Manufacturer Membership Application*, Healthcare Distribution Alliance,
<https://www.healthcaredistribution.org/~media/pdfs/membership/manufacturer-membership-application.ashx?la=en>.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

leaders and influential managers . . . to hold strategic business discussions on the most pressing industry issues.”⁴⁶² The conferences also gave the Manufacturer and Distributor Defendants “unmatched opportunities to network with [their] peers and trading partners at all levels of the healthcare distribution industry.”⁴⁶³ The HDA and its conferences were significant opportunities for the Manufacturer and Distributor Defendants to interact at a high-level of leadership. It is clear that the Manufacturer Defendants embraced this opportunity by attending and sponsoring these events.⁴⁶⁴

1113. After becoming members of HDA, Defendants were eligible to participate on councils, committees, task forces and working groups, including:

- a. Industry Relations Council: “This council, composed of distributor and manufacturer members, provides leadership on pharmaceutical distribution and supply chain issues.”
- b. Business Technology Committee: “This committee provides guidance to HDA and its members through the development of collaborative e-commerce business solutions. The committee’s major areas of focus within pharmaceutical distribution include information systems, operational integration and the impact of e-commerce.” Participation in this committee includes distributor and manufacturer members.
- c. Logistics Operation Committee: “This committee initiates projects designed to help members enhance the productivity, efficiency and customer satisfaction within the healthcare supply chain. Its major areas of focus include process automation, information systems, operational integration, resource management and quality improvement.” Participation in this committee includes distributor and manufacturer members.
- d. Manufacturer Government Affairs Advisory Committee: “This committee provides a forum for briefing HDA’s manufacturer members on federal and state legislative and regulatory activity affecting the pharmaceutical distribution channel. Topics discussed include such issues as prescription drug traceability, distributor licensing, FDA and DEA regulation of distribution, importation and

⁴⁶² *Business and Leadership Conference – Information for Manufacturers*, Healthcare Distribution Alliance, <https://www.healthcaredistribution.org/events/2015-business-and-leadership-conference/blc-for-manufacturers>.

⁴⁶³ *Id.*

⁴⁶⁴ *2015 Distribution Management Conference and Expo*, Healthcare Distribution Alliance, <https://www.healthcaredistribution.org/events/2015-distribution-management-conference>.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

Medicaid/Medicare reimbursement.” Participation in this committee includes manufacturer members.

e. Contracts and Chargebacks Working Group: “This working group explores how the contract administration process can be streamlined through process improvements or technical efficiencies. It also creates and exchanges industry knowledge of interest to contract and chargeback professionals.” Participation in this group includes manufacturer and distributor members.

1114. The Distributor Defendants and Manufacturer Defendants also participated, through the HDA, in Webinars and other meetings designed to exchange detailed information regarding their prescription opioid sales, including purchase orders, acknowledgements, ship notices, and invoices.⁴⁶⁵ For example, on April 27, 2011, the HDA offered a Webinar to “accurately and effectively exchange business transactions between distributors and manufacturers” The Manufacturer Defendants used this information to gather high-level data regarding overall distribution and direct the Distributor Defendants on how to most effectively sell prescription opioids.

1115. Taken together, the interaction and length of the relationships between and among the Manufacturer and Distributor Defendants reflects a deep level of interaction and cooperation between two groups in a tightly knit industry. The Manufacturer and Distributor Defendants were not two separate groups operating in isolation or two groups forced to work together in a closed system. Defendants operated together as a united entity, working together on multiple fronts, to engage in the unlawful sale of prescription opioids.

1116. The HDA and the PCF are but two examples of the overlapping relationships, and concerted joint efforts to accomplish common goals and demonstrates that the leaders of each of the Defendants were in communication and cooperation.

⁴⁶⁵ *Webinar Leveraging EDI: Order-to-Cash Transactions CD Box Set*, Healthcare Distribution Alliance, (Apr. 27, 2011), <https://www.healthcaredistribution.org/resources/webinar-leveraging-edi>.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

1117. Publications and guidelines issued by the HDA nevertheless confirm that the Defendants utilized their membership in the HDA to form agreements. Specifically, in the fall of 2008, the HDA published the Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances (the “Industry Compliance Guidelines”) regarding diversion. As the HDA explained in an amicus brief, the Industry Compliance Guidelines were the result of “[a] committee of HDMA members contribut[ing] to the development of this publication” beginning in late 2007.

1118. This statement by the HDA and the Industry Compliance Guidelines support the allegation that Defendants utilized the HDA to form agreements about their approach to their duties under the CSA. As John M. Gray, President/CEO of the HDA stated to the Energy and Commerce Subcommittee on Health in April 2014, is “difficult to find the right balance between proactive anti-diversion efforts while not inadvertently limiting access to appropriately prescribed and dispensed medications.” Here, it is apparent that all of the Defendants found the same balance – an overwhelming pattern and practice of failing to identify, report or halt suspicious orders, and failure to prevent diversion.

1119. The Defendants’ scheme had a decision-making structure driven by the Manufacturer Defendants and corroborated by the Distributor Defendants. The Manufacturer Defendants worked together to control the state and federal government’s response to the manufacture and distribution of prescription opioids by increasing production quotas through a systematic refusal to maintain effective controls against diversion, and identify suspicious orders and report them to the DEA.

1120. The Defendants worked together to control the flow of information and influence state and federal governments to pass legislation that supported the use of opioids and limited the

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

authority of law enforcement to rein in illicit or inappropriate prescribing and distribution. The Manufacturer and Distributor Defendants did this through their participation in the PCF and HDA.

1121. The Defendants also worked together to ensure that the Aggregate Production Quotas, Individual Quotas and Procurement Quotas allowed by the DEA remained artificially high and ensured that suspicious orders were not reported to the DEA in order to ensure that the DEA had no basis for refusing to increase or decrease production quotas due to diversion.

1122. The Defendants also had reciprocal obligations under the CSA to report suspicious orders of other parties if they became aware of them. Defendants were thus collectively responsible for each other's compliance with their reporting obligations.

1123. Defendants thus knew that their own conduct could be reported by other distributors or manufacturers and that their failure to report suspicious orders they filled could be brought to the DEA's attention. As a result, Defendants had an incentive to communicate with each other about the reporting of suspicious orders to ensure consistency in their dealings with DEA.

1124. The desired consistency was achieved. As described below, none of the Defendants reported suspicious orders and the flow of opioids continued unimpeded.

3. Distributor Defendants Marketed Manufacturers' Opioid Products

1125. Not only did the Distributor Defendants distribute, supply, and sell prescription opioids without fulfilling their duties to maintain effective controls against diversion, but also, the Distributor Defendants further increased the flood of opioids into Plaintiffs' communities by actively assisting manufacturers in marketing their opioid products.

1126. Distributors' efforts to assist manufacturers in increasing opioid prescriptions date back decades. For example, a 1991 article entitled "New Spirit of Partnering Rejuvenates Wholesalers" described efforts by the National Wholesale Druggists Association ("NWDA"), the predecessor entity to the HDMA/HDA, to work collaboratively with wholesalers, noting how

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

“wholesalers and manufacturers showed their optimism about the future of wholesale drugs,” in light of a “spirit of intercompany teamwork open[ing] up new opportunities for everyone involved....”⁴⁶⁶ Outgoing NWDA chairman Joseph Polastri was also quoted as stating that “suppliers and wholesalers have a common economic incentive to work more closely together.”

⁴⁶⁷

1127. In 1991, the NWDA organized official, high-level meetings between wholesalers and manufacturers. These visits, which were reported to have prompted discussions about using wholesaler sales representatives “to pass along technical product information to pharmacists, hospitals, third-party payers and perhaps even to selected doctors,” and several manufacturers also expressed interest “in tapping into wholesaler telemarketing capabilities.”⁴⁶⁸

1128. Manufacturers such as Purdue were members of the NWDA starting from the early 1990s.⁴⁶⁹ In a statement prepared by Purdue upon request of the NWDA, Purdue acknowledged the role that distributors’ marketing efforts played in its OxyContin launch, noting that “wholesaler incentive programs and advertising allowances” “wholesaler dating” and a variety of promotional programming offered by distributors such as “deal catalogs,” “retail tote stuffers,” “screen savers,” and “telemarketing” all helped Purdue exceed expectations within just the first five months of OxyContin’s availability.⁴⁷⁰ As Purdue explained, “[t]hrough the support of our wholesaler trading partners, availability at the retail level greatly contributed to this success.”⁴⁷¹ Distributor Defendants also helped facilitate the promotion of Manufacturer Defendants’ products at the retail

⁴⁶⁶ Val Cardinale, *New Spirit of Partnering Rejuvenates Wholesalers*, 135 Drug Topics 23 (Dec. 16, 1991).

⁴⁶⁷ *Id.*

⁴⁶⁸ NWDA Senior Management Teams Will Visit 30 Drug Companies By End Of Year; Wholesaler-Only Advisory Boards Have Been Established By 14 Drug Firms, *The Pink Sheet* (Nov. 25, 1991).

⁴⁶⁹ PKY180629088

⁴⁷⁰ PKY181012994

⁴⁷¹ PKY181012994

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

level. For example, in describing services offered by McKesson and AmerisourceBergen's predecessor entity, Bergen Brunswig, Purdue noted "Utilizing the drug wholesaler, incentives will be offered to facilitate placement of OxyContin at the retail level."⁴⁷² These Distributor marketing activities were an integral part of the Manufacturer Defendants' deceptive scheme to spread misrepresentations about opioids and increase opioid prescribing.

1129. Manufacturer Defendants worked with Distributor Defendants to develop marketing activities and paid Distributor Defendants for their efforts.

1130. As the Distributor Defendants' marketing activities drove dramatic increases in opioid prescriptions, Distributor Defendants continued distribute unconscionable quantities of opioids and both Distributor and Manufacturer Defendants continued to ignore their obligations to monitor, report, and stop suspicious orders. Distributors acted as more than middlemen or mere delivery services; on the contrary, they inserted themselves directly into doctor-patient relationships. The Distributor Defendants marketed opioids directly to patients, including for off-label and unsafe uses, and they also consulted with patients about using opioids. Together, the Supply Chain Defendants worked to overcome insurers' resistance to covering opioids outside of the uses for which they had been approved. For example, AmerisourceBergen and its Xcenda division paid in-house scientists to publish articles downplaying the risks of opioids. Like PBM Defendants, Distributor Defendants also engaged in marketing efforts by providing discount cards to induce consumers to purchase the Manufacturer Defendants' opioids. As a 2017 internal-Purdue document explains, "[t]here is evidence associating cash payment with opioid abuse and diversion" and "[d]iscount cards can lower the out of pocket cost for a cash prescription without revealing the identity of the card user."⁴⁷³ Moreover, as alleged in the Massachusetts Attorney

⁴⁷² PKY181732400

⁴⁷³ PPLPC021000919245

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

General Complaint, internal Purdue documents also revealed that opioid savings cards had the “highest return on investment” because they caused patients to stay on Purdue’s product for much longer. In sum, the Distributor Defendants continually engaged in marketing efforts for the Manufacturer Defendants for decades.

1131. The Defendants also had reciprocal obligations under the CSA to report suspicious orders of other parties if they became aware of them. Defendants were thus collectively responsible for each other’s compliance with their reporting obligations.

1132. Defendants thus knew that their own conduct could be reported by other distributors or manufacturers and that their failure to report suspicious orders they filled could be brought to the DEA’s attention. As a result, Defendants had an incentive to communicate with each other about the reporting of suspicious orders to ensure consistency in their dealings with DEA.

1133. The desired consistency was achieved. As described below, all of the Supply Chain Defendants repeatedly failed to report suspicious orders and the flow of opioids continued unimpeded.

J. The PBM Defendants Further Exacerbated the Flood of Opioids into the Market

1134. Together, the PBM Defendants control nearly 73 percent of the market share.

1135. Pharmacy Benefit Managers (PBMs) are companies that administer prescription drug plans for entities that include insurers, self-insured employers, and state and federal government agencies (collectively, these entities are referred to as “plan sponsors”). PBMs review and pay claims; PBMs also review and decide “which medications are most effective for each therapeutic use.”⁴⁷⁴ In effect, a PBM’s plan can determine what medications will (or will not) be

⁴⁷⁴http://www.americanhealthpolicy.org/Content/documents/resources/December%202015_AHPI%20Study_Understanding_the_Pharmaceutical_Box.pdf

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

available, at what quantity, and how difficult it may be for a prescriber to receive that medication (e.g., by requiring pre-authorization).

1136. In essence, because PBMs choose which drugs appear on their formularies, they wield significant influence over which drugs are disseminated throughout Plaintiffs' communities and how those drugs are paid for.

1137. Upon information and belief, PBM Defendants colluded with manufacturers who offer financial incentives, such as rebates and administrative fees, in exchange for benefit plan design, formulary placement, and drug utilization management that would result in more opioids entering the marketplace.

1138. “[N]early one third of all expenditures on branded drugs in 2015 were eventually rebated back. And, most of these rebates directly benefited the PBM.”⁴⁷⁵ Because of this, “PBMs earnings are enhanced when manufacturers charge high list prices, but then pay large rebates and discounts to lower the actual transaction prices...”⁴⁷⁶

1139. In addition to rebates, PBMs negotiate the payment of administrative fees, volume bonuses and other forms of consideration from manufacturers. The PBMs’ ability to negotiate these incentives from drug manufacturers derives from their control of the factors driving utilization, including formulary development and plan design.

1140. PBMs require, and receive, incentives from Manufacturer Defendants to keep certain drugs on and off formularies.

1141. These incentives include the payment of rebates by Manufacturer Defendants to PBMs based on utilization, bonuses for moving product and hitting volume targets, and the

⁴⁷⁵ Wayne Winegarten, To Improve Pharmaceutical Pricing, Reform PBMs and Fix Health Cares Systemic Problems, April 4, 2017, available at <https://www.forbes.com/sites/econostats/2017/04/04/to-improve-pharmaceutical-pricing-reform-pbms-and-fix-health-cares-systemic-problems/#648ab5593322>

⁴⁷⁶ *Id.*

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

payment of lucrative administrative fees to maximize PBM profits. Much of this activity is not transparent to anyone, including those who in good faith hire PBMs to manage their benefits.

1142. Upon information and belief, when PBMs were asked by their clients to implement greater safeguards that limited access to opioids, PBMs refused. Instead, the PBMs opted to receive lucrative rebates from drug manufacturers in exchange for making the manufacturers' prescription opioids as available and accessible as possible.

1143. By placing prescription opioids on their formularies and declining to impose appropriate limits on approval for its use, the PBM Defendants facilitated the proliferation and subsequent diversion of prescription opioids throughout West Virginia and within Cabell County and the City of Huntington in particular.

1144. For example, in 2001, when officials in the West Virginia state employee health plan sought to have OxyContin require pre-authorization, Purdue used the financial quid pro quo it had with the West Virginia PBM, it paid Merck Medco (now Express Scripts) to prevent insurers from limiting access to the drug.

1145. According to a former Purdue official responsible for ensuring favorable treatment for OxyContin, the strategy to pay Merck Medco extended to other big pharmacy benefit managers: "That was a national contract . . . We would negotiate a certain rebate percentage for keeping it on a certain tier related to copay or whether it has prior authorization. We like to keep prior authorization off of any drug."⁴⁷⁷

1146. Upon information and belief, this practice was prevalent for all PBM Defendants and Manufacturer Defendants. This practice was consistent nationwide: manufacturers provide

⁴⁷⁷ David Armstrong, *Drug maker thwarted plan to limit OxyContin prescriptions at dawn of opioid epidemic*. STAT (October 26, 2016), available at <https://www.statnews.com/2016/10/26/oxycontin-maker-thwarted-limits/>.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

financial incentives and, in return, the PBM Defendants agreed to make certain prescription opioids available without prior authorization and with low copayments.

1147. PBMs' complicity in the overall fraudulent scheme is knowing and purposeful. Manufacturers compete for PBM formulary placement (preferred placement results in greater utilization and greater profits) and pay PBMs incentives to avoid pre-authorization requirements and other hurdles that would slow down flow. Upon information and belief, the defendant PBM formularies include the majority of the opioids at issue in this case, often in preferred tiers, without quantity limits or prior authorization requirements.

1148. Moreover, at the same time that PBMs made it easier to obtain prescription opioids, they made it more difficult to receive treatment for addiction.

K. Collectively, the Defendants' Actions have had a Devastating Effect on Plaintiffs' Communities

1149. West Virginia has been particularly hard-hit by the opioid epidemic. The State had the highest drug-overdose death rate in the US in 2014, 2015, and 2016, according to a recent CDC report.⁴⁷⁸ The state also has one of the highest prescription rates of opioids in the United States.⁴⁷⁹ West Virginia ranks in the top 10 for the highest rate of prescriptions given out for high-dose opioids and extended-release opioids both of which are targets for abusers.

1150. For over a decade, West Virginia has been at the top, if not led the nation in prescription drug overdose deaths.⁴⁸⁰

⁴⁷⁸ <http://www.cdc.gov/drugoverdose/data/statedeaths.html>.

⁴⁷⁹ <http://www.businessinsider.com/these-are-the-states-prescribing-the-most-opioid-painkillers-2016-3>.

⁴⁸⁰ See Correspondence from Robert C. Knittle, Executive Director, State of West Virginia Board of Medicine to West Virginia Attorney General Patrick Morrisey dated August 9, 2016, located at <http://ago.wv.gov/Documents/2016.08.18%20BOM%20Letter.PDF>.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

1151. West Virginia leads the nation in opioid deaths and has a drug addiction problem that is devastating families and communities across the state.⁴⁸¹

1152. West Virginia has a high drug poisoning rate, according to the data drawn from the Vital Statistics of the National Center for Health Statistics, (NCHS). In 2014, West Virginia had a drug poisoning death rate of 35.5 per 100,000 persons, compared to the United States death rate of 14.7.⁴⁸² In 2017, there were 833 drug overdose deaths involving opioids in West Virginia – a rate of 49.6 deaths per 100,000 persons.⁴⁸³

1153. West Virginia has one of the highest rates of drug overdose deaths in the United States. West Virginia had 36.3 drug overdose deaths per 100,000 people in 2011, nearly triple the U.S. rate (13.2 per 100,000).⁴⁸⁴ Prescription drugs – opioids and benzodiazepines in particular – are major drivers of the drug overdose deaths in West Virginia.⁴⁸⁵

1154. West Virginia suffered a statistically significant increase in the drug overdose death rate from 2015 to 2016, according to data from the Centers for Disease Control and Prevention (CDC).⁴⁸⁶ The death rate rose by 25.3 percent.⁴⁸⁷

1155. According to the CDC, in 2016, 884 people died of drug overdoses in West Virginia, for a rate of 52.0 per 100,000 people making it the State with the highest overdose death

⁴⁸¹ See Correspondence from Louise Reese, CEO WV Primary Care Association to West Virginia Attorney General Patrick Morrisey date August 9, 2016, located at <http://ago.wv.gov/Documents/2016.08.18%20WVPCA%20Letter.PDF>.

⁴⁸² See CDC Drug Overdose Mortality by State “2014 Tab” located at https://www.cdc.gov/nchs/pressroom/sosmap/drug_poisoning_mortality/drug_poisoning.htm (last visited June 8, 2019).

⁴⁸³ See NIH National Institute on Drug Abuse, West Virginia Opioid Summary, Revised March 2019, located at <https://www.drugabuse.gov/opioid-summaries-by-state/west-virginia-opioid-summary>.

⁴⁸⁴ See Press Release, Centers for Disease Control and Prevention, “CDC awards over \$1 Million to West Virginia to address prescription drug overdose prevention” (August 14, 2014), located at https://www.cdc.gov/injury/pressroom/pressreleases/2014/pressrelease_pdo-wvirusnia.html.

⁴⁸⁵ *Id.*

⁴⁸⁶ Centers for Disease Control and Prevention, *Drug Overdose Death Data*, (“2015-2016 Death Increases” tab, available at <https://www.cdc.gov/drugoverdose/data/statedeaths.html> (last visited June 8, 2019)).

⁴⁸⁷ *Id.*

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

rate in the United States.⁴⁸⁸ In 2015, 725 people died from drug overdoses while in 2014, 627 people died, for a death rate of 41.5 deaths per 100,000 people, making it the State with the highest overdose death rate in the United States.⁴⁸⁹

1156. West Virginia also had the highest overdose death rate of any state in 2013 and 2014 with the rate increasing 10.2% during that time.⁴⁹⁰ The average age at death was 42 years old, for both men and women.⁴⁹¹

1157. Opioid prescribing rates in West Virginia are among the highest in the country. In 2012, West Virginia providers wrote 137.6 opioid pain reliever prescriptions per 100 people, the third highest prescribing rate in the country and far above the U.S. rate (82.5/100).⁴⁹²

1158. In March of 2017, a state fund to pay for burials for the poor ran out of money, five months before the end of the fiscal year.⁴⁹³

1159. West Virginia has long been known as “coal country.” Mining, timbering, and manufacturing play a huge role in West Virginia’s economy.⁴⁹⁴ They are all jobs that require heavy manual labor and leave workers prone to injury. Coal mining accounts for more than 18,000 jobs in West Virginia.⁴⁹⁵ Although West Virginia’s coal mines have lost more than 7,000 jobs since 2011, the mining industry as a whole has continued to grow in the state, thanks to strong

⁴⁸⁸ See CDC Drug Overdoses Mortality by State “2016 tab”, located at https://www.cdc.gov/nchs/pressroom/sosmap/drug_poisoning_mortality/drug_poisoning.htm (last visited on June 8, 2019).

⁴⁸⁹ See CDC Drug Overdoses Mortality by State “2015 tab” located at https://www.cdc.gov/nchs/pressroom/sosmap/drug_poisoning_mortality/drug_poisoning.htm (last visited on June 8, 2019).

⁴⁹⁰ See West Virginia Department of Health and Human Resources, Bureau for Public Health, West Virginia Drug Overdose Deaths Historical Overview 2001-2015, August 17, 2017, at *4, located at https://dhhr.wv.gov/oeps/disease/ob/documents/opioid/wv-drug-overdoses-2001_2015.pdf.

⁴⁹¹ *Id.* at 6.

⁴⁹² See Press Release, Centers for Disease Control and Prevention, “CDC awards over \$1 Million to West Virginia to address prescription drug overdose prevention” (August 14, 2014).

⁴⁹³ *Id.*

⁴⁹⁴ http://www.seniorjobbank.org/database/West_Virginia/West_Virginia.html.

⁴⁹⁵ http://www.nma.org/pdf/c_employment_state_region_method.pdf.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

growth in the natural gas and oil industries. According to the US Bureau of Economic Analysis, mining accounted for 18% of the state's overall GDP in 2014.⁴⁹⁶

1160. Mining operations proved to be flash points for opioid abuse when prescription practices liberalized, as workers tried to stave off injuries. John Temple, a professor at West Virginia University and the author of the 2015 book "American Pain", has offered:

*In a mining camp, there aren't a lot of doctors," he said. "That doctor is going to be more likely to opt for the quick fix and give people pills to fix their pain and get them back into the mine, rather than give them rest or therapy or those things that can actually cure pain.*⁴⁹⁷

1161. Dr. Carl "Rolly" Sullivan, who has run the addiction program at West Virginia University Hospitals since 1985, has noted the link between opioid abuse and the West Virginian economy:

*"West Virginia was ripe for the picking, We had a lot of blue-collar workers who were in farming and timbering and coal mining and things that were likely to produce injuries. There are a lot of dangerous occupations" in Appalachia, he said. "People get prescribed opioids far more frequently" for the injuries associated with them.*⁴⁹⁸

1162. The Huntington Mayor's Office of Drug Control Policy noted that "West Virginians working manual labor jobs disproportionately used prescription opioids for job-related injuries and chronic pain. As unemployment increased and the state cracked down on prescription drug use, opioid users turned to cheaper alternatives like heroin."

1163. Opioid abuse was further exacerbated by a declining economy and heavy job loss in the state over the last 20 years. As of March 2016, West Virginia has the second-highest unemployment rate in the US, at 6.5%. According to a Bureau of Labor Statistics report last

⁴⁹⁶<https://www.afsc.org/sites/afsc.civicactions.net/files/documents/Report-state-working-west-virginia-2014.pdf>.

⁴⁹⁷<http://www.amazon.com/American-Pain-Unleashed-Americas-Deadliest/dp/1493007386?tag=bisafetynet-20>.

⁴⁹⁸ <http://www.wvgazetteemail.com/apps/pbcs.dll/article?AID=/20151017/GZ01/151019539>.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

August, West Virginia was the only state to experience a statistically significant decrease in employment over the previous year, losing 19,100 jobs from 2014 to 2015.

1164. Though the coal-mining industry has been hit hard jobs in the sector have decreased from 41,000 in 1983 to approximately 18,000 in 2016,⁴⁹⁹ according to the Mine Safety and Health Administration, other West Virginian industries were struck as bad or worse. According to The Wall Street Journal, jobs in construction and manufacturing have fallen by 23% and 16%, respectively, since the recession.⁵⁰⁰

1165. Within West Virginia, the Plaintiffs' Community has been particularly ravaged by the opioid epidemic created and fueled by Defendants' wrongful actions.

1166. Cabell County's drug poisoning death rate is higher than the West Virginia drug poisoning death rate and has consistently exceeded the national average during the prescription opiate epidemic.

1167. Of the 100,000 people who live in Cabell County, an estimated 10,000 of them have become addicted to opioids.⁵⁰¹

1168. Cabell County had 1,476 drug overdose incidents in 2016, a 56% increase since 2015 and a 443% increase over the total number of overdoses in 2014.⁵⁰²

1169. In 2016, the youngest overdose victim in Cabell County was just eleven years old.⁵⁰³

⁴⁹⁹ <https://www.washingtonpost.com/news/wonk/wp/2013/11/04/heres-why-central-appalachias-coal-industry-is-dying/>.

⁵⁰⁰ <http://blogs.wsj.com/economics/2015/08/21/the-only-state-to-lose-jobs-since-july-last-year-west-virginia/>.

⁵⁰¹ See PBS News Hour, "A community overwhelmed by opioids" located at <https://www.pbs.org/newshour/show/community-overwhelmed-opioids>.

⁵⁰² See May 2017 Mayor's Office of Drug Control Policy "Two Year Strategic Plan for Addressing the Opioid Crisis in the City of Huntington/Cabell and Wayne Counties, West Virginia" at p. 2, available at http://www.cityofhuntington.com/assets/pdf/MODCP_two_year_plan_May_2017.pdf.

⁵⁰³ *Id.* at 1.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

In Cabell County alone, there were at least 32 overdose deaths and 360 drug overdoses, including heroin and prescription drugs in 2017.

1170. The Centers for Disease Control and Prevention has tracked prescription rates per county in the United States, identifying the geographic “hotspots” for rates of opioid prescriptions. The CDC has calculated the geographic distribution at county levels of opioid prescriptions dispensed per 100 persons,⁵⁰⁴ revealing that Cabell County has been a consistent hotspot over at least the past decade.

1171. According to data compiled by the CDC, in 2016, 122.3 opioid prescriptions were dispensed for every 100 people in Cabell County,⁵⁰⁵ which was above the national average of 66.5 prescriptions per 100 people.⁵⁰⁶ The overall opioid prescribing rate in 2015 was 70.6 prescriptions per 100 people.⁵⁰⁷ The 2015 Cabell County prescription rate was even higher than 2016 at 135.7 per 100 people.⁵⁰⁸

1172. Unfortunately, the 2015 and 2016 high rates of opioid prescriptions were not an aberration for Cabell County. Consistently, the opioid prescribing rates in Cabell County have been significantly greater than the national average and, in many years, close to one prescription per person. For example, compared to a national average of 75.6 opioid prescriptions per 100 people in 2014,⁵⁰⁹ the Cabell County opioid prescription rate was 148.8 per 100 people.⁵¹⁰

⁵⁰⁴ *Id.*

⁵⁰⁵ Centers for Disease Control and Prevention, U.S. County Prescribing Rates 2016, (reporting for “Cabell County, WV,” here and below) available <https://www.cdc.gov/drugoverdose/maps/rxcounty2016.html> (last visited June 8, 2019).

⁵⁰⁶ U.S. Prescribing Rate Maps, CDC, *supra*.

⁵⁰⁷ *Id.*

⁵⁰⁸ U.S. County Prescribing Rates, 2015, CDC, available at <https://www.cdc.gov/drugoverdose/maps/rxcounty2015.html> (last visited June 8, 2019).

⁵⁰⁹ U.S. Prescribing Rate Maps, CDC, *supra*.

⁵¹⁰ U.S. County Prescribing Rates, 2014, CDC, available at <https://www.cdc.gov/drugoverdose/maps/rxcounty2014.html> (last visited June 8, 2019).

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

1173. As a result of the increase in overdoses and use of naloxone, the community has sustained high costs related to first responders responding to overdose calls.⁵¹¹

1174. The Defendants' actions have also resulted in significant increases in crime and related criminal justice expenses.

1175. In 2018, the Huntington Police Department executed 100 warrant raids on suspected drug houses, nearly double the total 58 in 2017.⁵¹²

1176. In 2015, incarcerating low-level drug abusing offenders at a regional jail cost \$48.25 per day.⁵¹³

1177. The Cabell County Drug Court was designed for nonviolent offenders suffering drug dependency with the goal of reducing recidivism and substance abuse.⁵¹⁴ The intense program requires weekly meetings, random drug screens, support group meetings and employment, among other demands.⁵¹⁵ Cabell County has approximately 100 applications for Drug court a year.⁵¹⁶ The Community has expanded the Cabell County Drug Court to develop a specialized track that serves the needs of female prostitutes struggling with addiction.⁵¹⁷

1178. The Plaintiffs' Community is littered with abandoned buildings in once thriving, working-class neighborhoods, and has seen increases in drug-related crimes and drug use related vehicle accidents.⁵¹⁸ As a result, property values in the Plaintiffs' Community have decreased

⁵¹¹ See May 2017 Mayor's Office of Drug Control Policy, *supra*, at p. 11.

⁵¹² Bishop Nash, The Opioid Epidemic: Experts mull causes, relevance of Cabell County's overdose drop, March 10, 2019, Herald-Dispatch, located at https://www.herald-dispatch.com/the-opioid-epidemic-experts-mull-causes-relevance-of-cabell-county/article_55496c94-cc63-5864-850a-42e54cf94a5a.html

⁵¹³ See May 2017 Mayor's Office of Drug Control Policy, *supra*, at p. 11.

⁵¹⁴ Courtney Hessler, Drug Court's rigor worth it, participants say, Dec. 3, 2017, Herald-Dispatch, located at https://www.herald-dispatch.com/news/drug-court-s-rigor-worth-it-participants-say/article_651e39e1-fc0e-5512-917b-bfb500aa06fe.html.

⁵¹⁵ *Id.*

⁵¹⁶ *Id.*

⁵¹⁷ See May 2017 Mayor's Office of Drug Control Policy, *supra*, at p. 11.

⁵¹⁸ See May 2017 Mayor's Office of Drug Control Policy at p. 8.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

resulting in a decrease in tax revenue. Indeed, as of the end 2017, property values in the Plaintiffs' Community are decreasing at an almost 12% annual basis.⁵¹⁹

1179. In 2004, drug offenses primarily occurred within a two-block-by-two-block area in Huntington. By 2014, the opioid crisis has resulted in the city being bombarded with drug offenses occurring throughout the city. This example typifies the spread of the epidemic throughout Plaintiffs' Community.

⁵¹⁹ <https://www.neighborhoodscout.com/wv/huntington/real-estate> (Report Dated April 21, 2018).

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

Note: The colors in each map represent the concentration, or quantity, of drug offenses that occurred in a specific area and ranges from **green**, few drug offenses, to **red**, many drug offenses.

Source: Huntington, WV, Police Department

1180. One out of every four calls to the Huntington Fire Department involve cases of overdose.⁵²⁰ In 2015, the Huntington Fire Department responded to 3,500 calls. In 2016, the Huntington Fire Department responded to 4,500 calls. In 2017, the Huntington Fire Department was on track to respond to more than 5,500 calls. Huntington Fire Chief, Jan Rader, estimates that Huntington averages 5-7 overdoses a day.⁵²¹ Jan Rader was recently named to the Time's 100

⁵²⁰ *Id.*

⁵²¹ <https://www.forbes.com/sites/davidalm/2017/09/14/heroin-fights-three-women-fighting-west-virginias-opioid-epidemic/#60cfb9b71e6a>

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

Influential People List based on the work she has done on the front lines combating this epidemic on a daily basis.⁵²²

1181. Huntington has become known as the “overdose capital of the country” and was the subject of an Oscar nominated film “Heroin(e).”⁵²³

1182. A study published in the *American Journal of Public Health* estimates that 1,857 people injected drugs in Cabell County, West Virginia in the six months preceding publication on January 24, 2019.⁵²⁴ This study noted that twenty percent of West Virginia’s 2017 overdoses occurred in Cabell County.

1183. Used needles are scattered across the Plaintiffs’ Community’s parks, sidewalks and streets resulting in environmental contamination of the public and private property in the Community. According to Terry Watts of Huntington’s Park & Recreation District, needles have been “found in the playgrounds, . . . bathrooms, edges of parking lots, [and] boat ramp. I mean, the floods, the floodwater brings a bunch of them in down there.”⁵²⁵ Needles have also clogged storm water catch basins, threatening sanitation workers. According to Wesley Leek, Director of the Huntington Sanitary Board, the sanitation workers “may actually have to physically reach down and pull debris out. We use a needle-proof, cut-proof gloves to protect our employees from being stuck.”⁵²⁶

1184. The opioid crisis has coincided with increases in blood-borne infectious diseases tied to I.V. drug use (some of which were once describe as rare) are now common throughout the

⁵²² See <http://time.com/collection-post/5238151/jan-rader>.

⁵²³ <https://www.forbes.com/sites/davidalm/2017/09/14/heroin-foll...> three-women-fighting-west-virginias-opioid-epidemic/#60cfb9b71e6a

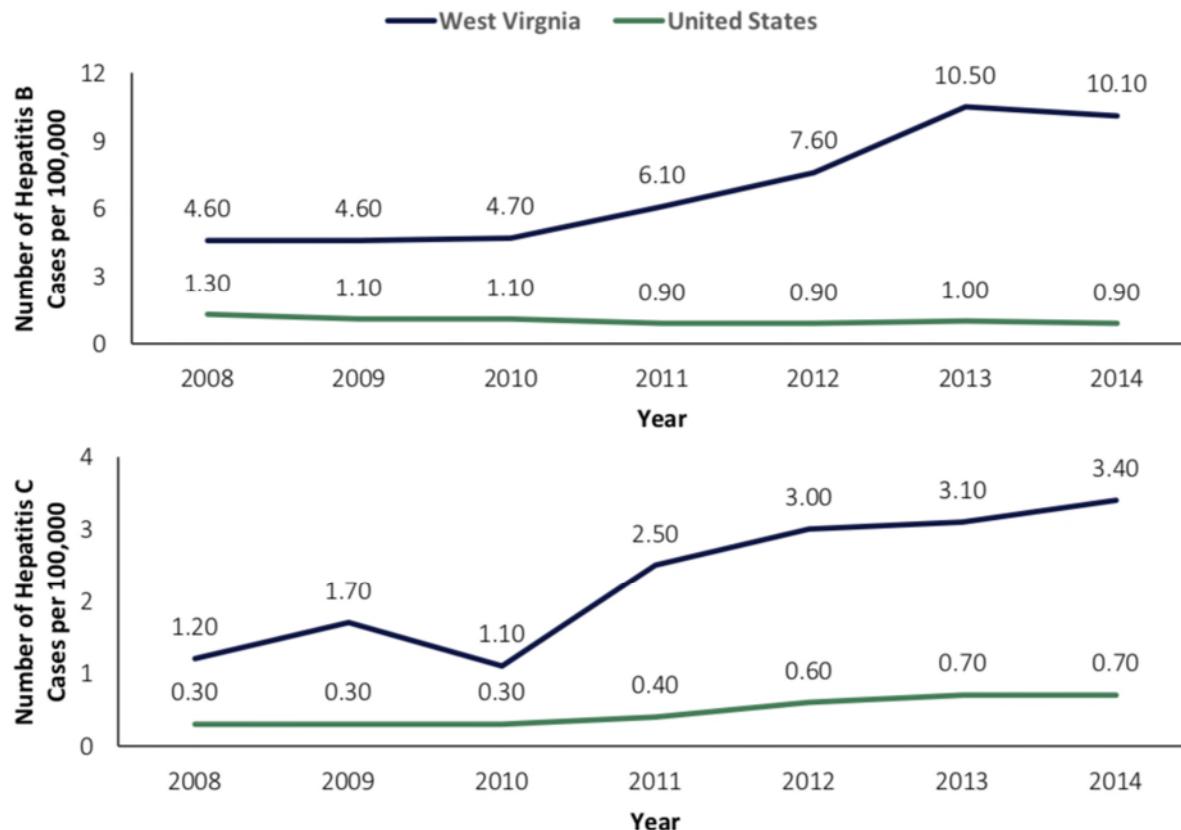
⁵²⁴ Sean T. Allen, Allison O’Rourke, Rebecca Hamilton White, Kristin E. Schneider, Michael Kilkenny, Susan G. Sherman, Estimating the Number of People Who Inject Drugs in A Rural Community in Appalachia, *American Journal of Public Health*, 2019, e1 DOI; <https://americanhealth.jhu.edu/RuralOpioidsCount>

⁵²⁵ See PBS News Hour, *supra*.

⁵²⁶ *Id.*

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

city of Huntington.⁵²⁷ West Virginia's severe opioid crisis led to larger increases in its incidence rate of hepatitis B and C over the period 2010-2014 compared with changes in the national rate. The state's incidence rate of hepatitis B was 10.10 cases per 100,000 population in 2014, which is the highest rate in the nation and more than 10 times the national rate; its incidence rate of hepatitis C is the second highest in the nation and about five times the nation rate.⁵²⁸



Source: Centers for Disease Control

1185. Cabell County is one of the 200 counties the Centers for Disease Control has identified as highly vulnerable to sudden outbreaks of hepatitis C or HIV.⁵²⁹ The Huntington Mayor's Office of Drug Control Policy has concluded that "the area's high incidence of such

⁵²⁷ *Id.*; see also May 2017 Mayor's Office of Drug Control Policy, *supra*.

⁵²⁸ *Id.*

⁵²⁹ See May 2017 Mayor's Office of Drug Control Policy at p. 6.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

diseases and vulnerability to outbreaks followed the decrease in illegally diverted prescription medication and rise in heroin use since 2010 and is considered a *public health emergency*.⁵³⁰

1186. The Cabell-Huntington Health Department has recently confirmed an active HIV cluster of 28 known cases in Cabell County, primarily among the area's population of intravenous drug users.⁵³¹ The cluster, tracked from January 2018 to March 2019 represents a dramatic increase from the baseline average of eight cases annually over the past five years.⁵³²

1187. In addition to an increase in diseases related to intravenous drug use, there were at least 406 drug-related arrests in Huntington in 2015⁵³³.

1188. In 2015, the Cabell-Huntington Health Department partnered with more than 30 local community agencies and organizations to create a comprehensive harm-reduction program which provides overdose prevention resources, drug treatment referrals and sterile injection equipment.⁵³⁴

1189. The Cabell-Huntington Health Department Harm Reduction Program provides syringe exchange; screening tests for HIV and hepatitis; peer recovery coaches; education, such as naloxone training; and health services, including primary care and chronic disease management, and referrals to treatment programs and support services.⁵³⁵ During the first nine months, the

⁵³⁰ *Id.* at 6.

⁵³¹ Bishop Nash, HIV Cluster Found in West Virginia County with High Rate of Opioid Use, March 6, 2019, PolitiFact West Virginia, located at <https://www.100daysinappalachia.com/2019/03/06/hiv-cluster-found-in-west-virginia-county-with-high-rate-of-opioid-use/>

⁵³² *Id.*

⁵³³ <http://www.dailymail.co.uk/news/article-3128229/West-Virginia-rate-drug-overdose-deaths.html#ixzz4W7qD5w3j>

⁵³⁴ *Id.*

⁵³⁵ See May 2017 Mayor's Office of Drug Control Policy at p. 7.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

program had almost 4,000 visits with about 150 clients each week.⁵³⁶ Nearly ninety percent of the Harm Reduction Program clients listed opioids as a drug of choice.⁵³⁷

The loss of life has been devastating to the community that cannot be conveyed by statistics. And, the harm extends well beyond overdoses themselves. Meanwhile, residential treatment centers struggle to keep pace with the demand for addiction treatment services.

1190. As of October 2015, West Virginia had 750 treatment beds, and all facilities had a long waitlist.⁵³⁸ While the number of beds has increased, the demand still far exceeds the supply of treatment beds as more than 150,000 West Virginians struggle with substance abuse and addiction.⁵³⁹ As of 2017, Huntington's largest residential recovery facility had 100 beds and a waitlist of up to six months.⁵⁴⁰ The Huntington Comprehensive Treatment Center serves 1,000 patients every day and is at capacity, and the handful of facilities and physicians providing medication-assisted treatment have a waitlist as long as 18 months.⁵⁴¹

1191. In 2017, Cabell County and the City of Huntington launched a Quick Response Team consisting of a paramedic, a police officer, somebody in the recovery community, and somebody in the faith community.⁵⁴² The QRT visits people who have overdosed within 72 hours of resuscitation, to talk, listen, build a rapport with the patient and offer treatment options.⁵⁴³ Thirty percent of the people who have interacted with the QRT have accepted some form of help.⁵⁴⁴

⁵³⁶ *Id.*

⁵³⁷ Bishop Nash, The Opioid Epidemic: Experts mull causes, relevance of Cabell County's overdose drop, March 10, 2019, Herald-Dispatch, located at https://www.herald-dispatch.com/the-opioid-epidemic-experts-mull-causes-relevance-of-cabell-county/article_55496c94-cc63-5864-850a-42e54cf94a5a.html.

⁵³⁸ See May 2017 Mayor's Office of Drug Control Policy at p. 8.

⁵³⁹ *Id.*

⁵⁴⁰ *Id.*

⁵⁴¹ *Id.*

⁵⁴² Caroline Praderio, A fire chief in West Virginia helped change her city's approach to the opioid epidemic, Jan. 14, 2019, Insider.com, located at <https://www.insider.com/west-virginia-fire-chief-jan-rader-opioid-epidemic-ted-talk-2018-12>.

⁵⁴³ *Id.*

⁵⁴⁴ *Id.*

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

1192. The City of Huntington has started a self-care program for first responders who are experiencing “compassion fatigue and PTSD.”⁵⁴⁵

1193. The opioid crisis has created a strain on the foster care system which serves Plaintiffs’ Community’s, as it is now is “stretched dangerously thin.”

1194. Between 2009 and 2014, the percent of children nationwide with parental drug abuse as the reason for a child to be removed from a home increased from 22.1 percent to 29.7 percent.⁵⁴⁶

1195. A Senate Report noted that “[i]ncreasing numbers of children entering foster care, living with grandparents, or entering the world dependent on opioids will have consequences for decades to come” as many of those children “dealing with the childhood trauma of a parent addicted to opioids have suffered severe physical and mental distress, and some researchers speculate that the damage may be behind the recent rise in suicides among children and teenagers.”⁵⁴⁷

⁵⁴⁵ *Id.*

⁵⁴⁶ See Social Capital Project, SCP Report No.2-17, The Numbers Behind the Opioid Crisis, Prepared by the Vice Chairman’s Staff of the Joint Economic Committee at the Request of Senator Mike Lee, November 2017, at *37, located at https://www.lee.senate.gov/public/_cache/files/b54a2abb-978d-4bbb-a868-531cdfaeae7a/the-numbers-behind-the-opioid-crisis-final.pdf.

⁵⁴⁷ *Id.* at 39.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

1196. At Cabell Huntington Hospital, one out of every five babies delivered has been exposed to drugs before they were born.⁵⁴⁸ In response, the hospital had to create a unit specifically to care for the newborns as they go through withdrawal for drugs like painkillers, heroin, fentanyl and gabapentin.⁵⁴⁹ In 2014, more than 275 babies were born with NAS in Huntington area hospitals, and the incidence of NAS in Cabell County is 10 times higher than the national average.⁵⁵⁰ The state's incidence rate of NAS increased over the period 2009-2012 from 13.90 to 24.50 per 1,000 population and was estimated to be 49.9 in 2016.⁵⁵¹ In response, the County is in the process of developing a primary prevention initiative which will educate women with a history of substance abuse about NAS and voluntary long-acting reversible contraceptive options; will help women access the program and treatment services; establish a 24-hour call line; and provide train and bus fare for those who lack access to transportation.⁵⁵²

1197. Rising opioid use and abuse have negative social and economic consequences far beyond overdoses in other respects as well. According to a recent analysis by a Princeton University economist, approximately one out of every three working age men who are not in the labor force take daily prescription pain medication. The same research finds that opioid prescribing alone accounts for 20% of the overall decline in the labor force participation for this group from 2014-16, and 25% of the decline in labor force participation among women. Many of those taking painkillers still said they experienced pain daily.

⁵⁴⁸ See PBS Hour, supra.

⁵⁴⁹ *Id.*

⁵⁵⁰ See May 2017 Mayor's Office of Drug Control Policy at p. 7.

⁵⁵¹ *Id.*

⁵⁵² *Id.*

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

L. Statute of Limitations are Tolled and Defendants Are Estopped From Asserting Statutes of Limitations as Defenses

1. Continuing Conduct

1198. Plaintiff contends that it continues to suffer harm from the unlawful actions by the Defendants.

1199. The continued tortious and unlawful conduct by the Defendants causes a repeated or continuous injury. The damages have not occurred all at once but have continued to occur and have increased as time progresses. The tort is not completed nor have all the damages been incurred until the wrongdoing ceases. The wrongdoing and unlawful activity by Defendants has not ceased. The public nuisance remains unabated. The conduct causing the damages remains unabated.

2. Equitable Estoppel and Fraudulent Concealment

1200. Defendants are equitably estopped from relying upon a statute of limitations defense because they undertook active efforts to deceive Plaintiff and to purposefully conceal their unlawful conduct and fraudulently assure the public, including the State, the Plaintiff, and Plaintiff's community, that they were undertaking efforts to comply with their obligations under the state and federal controlled substances laws, all with the goal of protecting their registered manufacturer or distributor status in the State and to continue generating profits. Notwithstanding the allegations set forth above, the Defendants affirmatively assured the public, including the State, the Plaintiff, and Plaintiff's community, that they are working to curb the opioid epidemic.

1201. The Defendants were deliberate in taking steps to conceal their conspiratorial behavior and active role in the deceptive marketing and the oversupply of opioids through overprescribing and suspicious sales, all of which fueled the opioid epidemic.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

1202. As set forth herein, the Marketing Defendants deliberately worked through Front Groups purporting to be patient advocacy and professional organizations, through public relations companies hired to work with the Front Groups and through paid KOLs to secretly control messaging, influence prescribing practices and drive sales. The Marketing Defendants concealed their role in shaping, editing, and approving the content of prescribing guidelines, informational brochures, KOL presentations and other false and misleading materials addressing pain management and opioids that were widely disseminated to regulators, prescribers and the public at large. They concealed the addictive nature and dangers associated with opioid use and denied blame for the epidemic attributing it instead solely to abuse and inappropriate prescribing. They manipulated scientific literature and promotional materials to make it appear that misleading statements about the risks, safety and superiority of opioids were actually accurate, truthful, and supported by substantial scientific evidence. Through their public statements, omissions, marketing, and advertising, the Marketing Defendants' deceptions deprived Plaintiff of actual or implied knowledge of facts sufficient to put Plaintiff on notice of potential claims.

1203. Defendants also concealed from Plaintiff the existence of Plaintiff's claims by hiding their lack of cooperation with law enforcement and affirmatively seeking to convince the public that their legal duties to report suspicious sales had been satisfied through public assurances that they were working to curb the opioid epidemic. They publicly portrayed themselves as committed to working diligently with law enforcement and others to prevent diversion of these dangerous drugs and curb the opioid epidemic, and they made broad promises to change their ways insisting they were good corporate citizens. These repeated misrepresentations misled regulators, prescribers and the public, including Plaintiff, and deprived Plaintiff of actual or implied knowledge of facts sufficient to put Plaintiff on notice of potential claims.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

1204. Plaintiff did not discover the nature, scope and magnitude of Defendants' misconduct, and its full impact on Plaintiff, and could not have acquired such knowledge earlier through the exercise of reasonable diligence.

1205. The Marketing Defendants' campaign to misrepresent and conceal the truth about the opioid drugs that they were aggressively pushing in the State and in Plaintiff's community deceived the medical community, consumers, the State, and Plaintiff's community.

1206. Further, Defendants have also concealed and prevented discovery of information, including data from the ARCOS database, that would have confirmed their identities and the extent of their wrongful and illegal activities. On April 11, 2018, the Northern District of Ohio Ordered the transactional ARCOS data be produced, over Defendants' strenuous objections. In so doing, the Court reviewed its previous decisions on this data and held that, because the transaction data had not yet been produced, the Plaintiff *could not identify* the potential defendants in this litigation, and further held that such information was "critical":

This means Plaintiff[s] still do[] not know: (a) which manufacturers (b) sold what types of pills (c) to which distributors; nor do they know (d) which distributors (e) sold what types of pills (f) to which retailers (g) in what locations. In any given case, therefore, the Plaintiff[s] still cannot know for sure who are the correct defendants, or the scope of their potential liability. For example, the ARCOS spreadsheets produced by DEA show the top five distributors of oxycodone in Ohio in 2014 were Cardinal Health, AmerisourceBergen, McKesson, Walmart, and Miami-Luken; but there is no way to know whether (or how much) any of these five entities distributed oxycodone into Seneca County, Ohio (or any other particular venue). . . [The] DEA and [the] defendants . . . [have] conceded the data was relevant and necessary to litigation Discovery of precisely which manufacturers sent which drugs to which distributors, and which distributors sent which drugs to which pharmacies and doctors, is critical not only to all of plaintiff[s'] claims, but also to the Court's understanding of the width and depth of this litigation.

Order of April 11, 2018 [Doc. 233] at pp. 6-7 (footnotes omitted).

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

1207. Defendants intended that their actions and omissions would be relied upon, including by Plaintiff and Plaintiff's community. Plaintiff and Plaintiff's community did not know and did not have the means to know the truth, due to Defendants' actions and omissions.

1208. The Plaintiff and Plaintiff's community reasonably relied on Defendants' affirmative statements regarding their purported compliance with their obligations under the law and consent orders.

II. FACTS PERTAINING TO CLAIMS UNDER THE RACKETEER-INFLUENCED AND CORRUPT ORGANIZATIONS (“RICO”) ACT

A. The Opioid Marketing Enterprise

1. The Common Purpose and Scheme of the Opioid Marketing Enterprise

1209. Knowing that their products were highly addictive, ineffective and unsafe for the treatment of long-term chronic pain, non-acute and non-cancer pain, the RICO Marketing Defendants⁵⁵³ formed an association-in-fact enterprise and engaged in a scheme to unlawfully increase their profits and sales, and grow their share of the prescription painkiller market, through repeated and systematic misrepresentations about the safety and efficacy of opioids for treating long-term chronic pain.

1210. In order to unlawfully increase the demand for opioids, the RICO Marketing Defendants formed an association-in-fact enterprise (the “Opioid Marketing Enterprise”) with the “Front Groups” and KOLs described above. Through their personal relationships, the members of the Opioid Marketing Enterprise had the opportunity to form and take actions in furtherance of the Opioid Marketing Enterprise’s common purpose. The RICO Marketing Defendants’ substantial

⁵⁵³ The RICO Marketing Defendants referred to in this section are those named in the First Claim for Relief under 28 U.S.C. § 1964(c), including Purdue, Cephalon, Janssen, Endo, and Mallinckrodt.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

financial contribution to the Opioid Marketing Enterprise, and the advancement of opioids-friendly messaging, fueled the U.S. opioids epidemic.

1211. The RICO Marketing Defendants, through the Opioid Marketing Enterprise, concealed the true risks and dangers of opioids from the medical community and the public, including Plaintiff, and made misleading statements and misrepresentations about opioids that downplayed the risk of addiction and exaggerated the benefits of opioid use. The misleading statements included: (1) that addiction is rare among patients taking opioids for pain; (2) that addiction risk can be effectively managed; (3) that symptoms of addiction exhibited by opioid patients are actually symptoms of an invented condition the RICO Marketing Defendants named “pseudoaddiction”; (4) that withdrawal is easily managed; (5) that increased dosing present no significant risks; (6) that long-term use of opioids improves function; (7) that the risks of alternative forms of pain treatment are greater than the adverse effects of opioids; (8) that use of time-released dosing prevents addiction; and (9) that abuse-deterrent formulations provide a solution to opioid abuse.

1212. The scheme devised, implemented and conducted by the RICO Marketing Defendants was a common course of conduct designed to ensure that the RICO Marketing Defendants unlawfully increased their sales and profits through concealment and misrepresentations about the addictive nature and effective use of the RICO Marketing Defendants’ drugs. The RICO Marketing Defendants, the Front Groups, and the KOLs acted together for a common purpose and perpetuated the Opioid Marketing Enterprise’s scheme, including through the unbranded promotion and marketing network as described above.

1213. There was regular communication between the RICO Marketing Defendants, Front Groups and KOLs, in which information was shared, misrepresentations were coordinated, and

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

payments were exchanged. Typically, the coordination, communication and payment occurred, and continues to occur, through the repeated and continuing use of the wires and mail in which the RICO Marketing Defendants, Front Groups, and KOLs share information regarding overcoming objections and resistance to the use of opioids for chronic pain. The RICO Marketing Defendants, Front Groups and KOLs functioned as a continuing unit for the purpose of implementing the Opioid Marketing Enterprise's scheme and common purpose, and each agreed and took actions to hide the scheme and continue its existence.

1214. At all relevant times, the Front Groups were aware of the RICO Marketing Defendants' conduct, were knowing and willing participants in and beneficiaries of that conduct. Each Front Group also knew, but did not disclose, that the other Front Groups were engaged in the same scheme, to the detriment of consumers, prescribers, and the Plaintiff. But for the Opioid Marketing Enterprise's unlawful fraud, the Front Groups would have had incentive to disclose the deceit by the RICO Marketing Defendants and the Opioid Marketing Enterprise to their members and constituents. By failing to disclose this information, Front Groups perpetuated the Opioid Marketing Enterprise's scheme and common purpose, and reaped substantial benefits.

1215. At all relevant times, the KOLs were aware of the RICO Marketing Defendants' conduct, were knowing and willing participants in that conduct, and reaped benefits from that conduct. The RICO Marketing Defendants selected KOLs solely because they favored the aggressive treatment of chronic pain with opioids. The RICO Marketing Defendants' support helped the KOLs become respected industry experts. And, as they rose to prominence, the KOLs falsely touted the benefits of using opioids to treat chronic pain, repaying the RICO Marketing Defendants by advancing their marketing goals. The KOLs also knew, but did not disclose, that the other KOLS and Front Groups were engaged in the same scheme, to the detriment of

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

consumers, prescribers, and the Plaintiff. But for the Opioid Marketing Enterprise's unlawful conduct, the KOLs would have had incentive to disclose the deceit by the RICO Marketing Defendants and the Opioid Marketing Enterprise, and to protect their patients and the patients of other physicians. By failing to disclose this information, KOLs furthered the Opioid Marketing Enterprise's scheme and common purpose, and reaped substantial benefits.

1216. As public scrutiny and media coverage focused on how opioids ravaged communities in West Virginia and throughout the United States, the Front Groups and KOLS did not challenge the RICO Marketing Defendants' misrepresentations, seek to correct their previous misrepresentations, terminate their role in the Opioid Marketing Enterprise, nor disclose publicly that the risks of using opioids for chronic pain outweighed their benefits and were not supported by medically acceptable evidence.

1217. The RICO Marketing Defendants, Front Groups and KOLs engaged in certain discrete categories of activities in furtherance of the common purpose of the Opioid Marketing Enterprise. As described herein, the Opioid Marketing Enterprise's conduct in furtherance of the common purpose of the Opioid Marketing Enterprise involved: (1) misrepresentations regarding the risk of addiction and safe use of prescription opioids for long-term chronic pain (described in detail above); (2) lobbying to defeat measures to restrict over-prescription; (3) efforts to criticize or undermine CDC guidelines; and (4) efforts to limit prescriber accountability.

1218. In addition to disseminating misrepresentations about the risks and benefits of opioids, the Opioid Marketing Enterprise also furthered its common purpose by criticizing or undermining CDC Guideline. Members of the Opioid Marketing Enterprise criticized or undermined the CDC Guideline, which represented "an important step—and perhaps the first major step from the federal government—toward limiting opioid prescriptions for chronic pain."

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

1219. Several Front Groups, including the U.S. Pain Foundation and the AAPM, criticized the draft guidelines in 2015, arguing that the “CDC slides presented on Wednesday were not transparent relative to process and failed to disclose the names, affiliation, and conflicts of interest of the individuals who participated in the construction of these guidelines.”

1220. The AAPM criticized the prescribing guidelines in 2016, through its immediate past president, stating “that the CDC guideline makes disproportionately strong recommendations based upon a narrowly selected portion of the available clinical evidence.”

1221. The RICO Marketing Defendants alone could not have accomplished the purpose of the Opioid Marketing Enterprise without the assistance of the Front Groups and KOLs, who were perceived as “neutral” and more “scientific” than the RICO Marketing Defendants themselves. Without the work of the Front Groups and KOLs in spreading misrepresentations about opioids, the Opioid Marketing Enterprise could not have achieved its common purpose.

1222. The impact of the Opioid Marketing Enterprise’s scheme is still in place—*i.e.*, the opioids continue to be prescribed and used for chronic pain in West Virginia and the epidemic continues to injure Plaintiff, and consume the resources of Plaintiff’s health care and law enforcement systems.

1223. As a result, it is clear that the RICO Marketing Defendants, the Front Groups, and the KOLs were each willing participants in the Opioid Marketing Enterprise, had a common purpose and interest in the object of the scheme, and functioned within a structure designed to effectuate the Enterprise’s purpose.

2. The Conduct of the Opioid Marketing Enterprise violated Civil RICO

1224. From approximately the late 1990s to the present, each of the RICO Marketing Defendants exerted control over the Opioid Marketing Enterprise and participated in the operation

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

or management of the affairs of the Opioid Marketing Enterprise, directly or indirectly, in the following ways:

- a. Creating and providing a body of deceptive, misleading and unsupported medical and popular literature about opioids that (i) understated the risks and overstated the benefits of long-term use; (ii) appeared to be the result of independent, objective research; and (iii) was thus more likely to be relied upon by physicians, patients, and payors;
- b. Creating and providing a body of deceptive, misleading and unsupported electronic and print advertisements about opioids that (i) understated the risks and overstated the benefits of long-term use; (ii) appeared to be the result of independent, objective research; and (iii) was thus more likely to be relied upon by physicians, patients, and payors;
- c. Creating and providing a body of deceptive, misleading and unsupported sales and promotional training materials about opioids that (i) understated the risks and overstated the benefits of long-term use; (ii) appeared to be the result of independent, objective research; and (iii) was thus more likely to be relied upon by physicians, patients, and payors;
- d. Creating and providing a body of deceptive, misleading and unsupported CMEs and speaker presentations about opioids that (i) understated the risks and overstated the benefits of long-term use; (ii) appeared to be the result of independent, objective research; and (iii) was thus more likely to be relied upon by physicians, patients, and payors;
- e. Selecting, cultivating, promoting and paying KOLs based solely on their willingness to communicate and distribute the RICO Marketing Defendants' messages about the use of opioids for chronic pain;
- f. Providing substantial opportunities for KOLs to participate in research studies on topics the RICO Marketing Defendants suggested or chose, with the predictable effect of ensuring that many favorable studies appeared in the academic literature;
- g. Paying KOLs to serve as consultants or on the RICO Marketing Defendants' advisory boards, on the advisory boards and in leadership positions on Front Groups, and to give talks or present CMEs, typically over meals or at conferences;
- h. Selecting, cultivating, promoting, creating and paying Front Groups based solely on their willingness to communicate and distribute the RICO Marketing Defendants' messages about the use of opioids for chronic pain;
- i. Providing substantial opportunities for Front Groups to participate in and/or publish research studies on topics the RICO Marketing Defendants suggested or chose (and paid for), with the predictable effect of ensuring that many favorable studies appeared in the academic literature;

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

- j. Paying significant amounts of money to the leaders and individuals associated with Front Groups;
- k. Donating to Front Groups to support talks or CMEs, that were typically presented over meals or at conferences;
- l. Disseminating many of their false, misleading, imbalanced, and unsupported statements through unbranded materials that appeared to be independent publications from Front Groups;
- m. Sponsoring CME programs put on by Front Groups that focused exclusively on the use of opioids for chronic pain;
- n. Developing and disseminating pro-opioid treatment guidelines with the help of the KOLs as authors and promoters, and the help of the Front Groups as publishers, and supporters;
- o. Encouraging Front Groups to disseminate their pro-opioid messages to groups targeted by the RICO Marketing Defendants, such as veterans and the elderly, and then funding that distribution;
- p. Concealing their relationship to and control of Front Groups and KOLs from the Plaintiff and the public at large; and
- q. Intending that Front Groups and KOLs would distribute through the U.S. mail and interstate wire facilities, promotional and other materials that claimed opioids could be safely used for chronic pain.

1225. The Opioid Marketing Enterprise had a hierarchical decision-making structure that was headed by the RICO Marketing Defendants and corroborated by the KOLs and Front Groups. The RICO Marketing Defendants controlled representations made about their opioids and their drugs, doled out funds to PBMs and payments to KOLs, and ensured that representations made by KOLs, Front Groups, and the RICO Marketing Defendants' sales detailers were consistent with the Marketing Defendants' messaging throughout the United States and West Virginia. The Front Groups and KOLS in the Opioid Marketing Enterprise were dependent on the RICO Marketing Defendants for their financial structure and for career development and promotion opportunities.

1226. The Front Groups also conducted and participated in the conduct of the Opioid Marketing Enterprise, directly or indirectly, in the following ways:

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

- a. The Front Groups promised to, and did, make representations regarding opioids and the RICO Marketing Defendants' drugs that were consistent with the RICO Marketing Defendants' messages;
- b. The Front Groups distributed, through the U.S. Mail and interstate wire facilities, promotional and other materials which claimed that opioids could be safely used for chronic pain without addiction, and misrepresented the benefits of using opioids for chronic pain outweighed the risks;
- c. The Front Groups echoed and amplified messages favorable to increased opioid use—and ultimately, the financial interests of the RICO Marketing Defendants;
- d. The Front Groups issued guidelines and policies minimizing the risk of opioid addiction and promoting opioids for chronic pain;
- e. The Front Groups strongly criticized the 2016 guidelines from the Center for Disease Control and Prevention (CDC) that recommended limits on opioid prescriptions for chronic pain; and
- f. The Front Groups concealed their connections to the KOLs and the RICO Marketing Defendants.

1227. The RICO Marketing Defendants' Front Groups, "with their large numbers and credibility with policymakers and the public—have 'extensive influence in specific disease areas.'" The larger Front Groups "likely have a substantial effect on policies relevant to their industry sponsors."⁵⁵⁴ "By aligning medical culture with industry goals in this way, many of the groups described in the [*Fueling an Epidemic*] report may have played a significant role in creating the necessary conditions for the U.S. opioid epidemic."⁵⁵⁵

1228. The KOLs also participated in the conduct of the affairs of the Opioid Marketing Enterprise, directly or indirectly, in the following ways:

- a. The KOLs promised to, and did, make representations regarding opioids and the RICO Marketing Defendants' drugs that were consistent with the RICO Marketing Defendants' messages themselves;
- b. The KOLs distributed, through the U.S. Mail and interstate wire facilities, promotional and other materials which claimed that opioids could be safely used for

⁵⁵⁴ *Fueling an Epidemic*, *supra* note 17, at 1.

⁵⁵⁵ *Id.* at 2.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

chronic pain without addiction, and misrepresented the benefits of using opioids for chronic pain outweighed the risks;

- c. The KOLs echoed and amplified messages favorable to increased opioid use—and ultimately, the financial interests of the RICO Marketing Defendants;
- d. The KOLs issued guidelines and policies minimizing the risk of opioid addiction and promoting opioids for chronic pain;
- e. The KOLs strongly criticized the 2016 guidelines from the Center for Disease Control and Prevention (CDC) that recommended limits on opioid prescriptions for chronic pain; and
- f. The KOLs concealed their connections to the Front Groups and the RICO Marketing Defendants, and their sponsorship by the RICO Marketing Defendants.

1229. The scheme devised and implemented by the RICO Marketing Defendants and members of the Opioid Marketing Enterprise, amounted to a common course of conduct intended to increase the RICO Marketing Defendants' sales from prescription opioids by encouraging the prescribing and use of opioids for long-term chronic pain. The scheme was a continuing course of conduct, and many aspects of it continue through to the present.

3. The RICO Marketing Defendants Controlled and Paid Front Groups and KOLs to Promote and Maximize Opioid Use

1230. As discussed in detail above, the RICO Marketing Defendants funded and controlled the various Front Groups, including APF, AAPM/APS, FSMB, Alliance for Patient Access, USPF, and AGS. The Front Groups, which appeared to be independent, but were not, transmitted the RICO Marketing Defendants' misrepresentations. The RICO Marketing Defendants and the Front Groups thus worked together to promote the goals of the Opioid Marketing Enterprise.

1231. The RICO Marketing Defendants worked together with each other through the Front Groups that they jointly funded and through which they collaborated on the joint promotional materials described above.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

1232. Similarly, as discussed in detail above, the RICO Marketing Defendants paid KOLs, including Drs. Portenoy, Fine, Fishman, and Webster, to spread their misrepresentations and promote their products. The RICO Marketing Defendants and the KOLs thus worked together to promote the goals of the Opioid Marketing Enterprise.

1233. Pattern of Racketeering Activity

1234. The RICO Marketing Defendants' scheme described herein was perpetrated, in part, through multiple acts of mail fraud and wire fraud, constituting a pattern of racketeering activity as described herein.

1235. The pattern of racketeering activity used by the RICO Marketing Defendants and the Opioid Marketing Enterprise likely involved thousands of separate instances of the use of the U.S. Mail or interstate wire facilities in furtherance of the unlawful Opioid Marketing Enterprise, including essentially uniform misrepresentations, concealments and material omissions regarding the beneficial uses and non-addictive qualities for the long-term treatment of chronic, non-acute and non-cancer pain, with the goal of profiting from increased sales of the RICO Marketing Defendants' drugs induced by consumers, prescribers, regulators and Plaintiff's reliance on the RICO Marketing Defendants' misrepresentations.

1236. Each of these fraudulent mailings and interstate wire transmissions constitutes racketeering activity and collectively, these violations constitute a pattern of racketeering activity, through which the RICO Marketing Defendants, the Front Groups and the KOLs defrauded and intended to defraud West Virginia consumers, the State, and other intended victims.

1237. The RICO Marketing Defendants devised and knowingly carried out an illegal scheme and artifice to defraud by means of materially false or fraudulent pretenses, representations, promises, or omissions of material facts regarding the safe, non-addictive and

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

effective use of opioids for long-term chronic, non-acute and non-cancer pain. The RICO Marketing Defendants and members of the Opioid Marketing Enterprise knew that these representations violated the FDA approved use these drugs, and were not supported by actual evidence. The RICO Marketing Defendants intended that that their common purpose and scheme to defraud would, and did, use the U.S. Mail and interstate wire facilities, intentionally and knowingly with the specific intent to advance, and for the purpose of executing, their illegal scheme.

1238. By intentionally concealing the material risks and affirmatively misrepresenting the benefits of using opioids for chronic pain to prescribers, regulators and the public, including Plaintiff, the RICO Marketing Defendants, the Front Groups and the KOLs engaged in a fraudulent and unlawful course of conduct constituting a pattern of racketeering activity.

1239. The RICO Marketing Defendants' use of the U.S. Mail and interstate wire facilities to perpetrate the opioids marketing scheme involved thousands of communications, publications, representations, statements, electronic transmissions, payments, including, *inter alia*:

- a. Marketing materials about opioids, and their risks and benefits, which the RICO Marketing Defendants sent to health care providers, transmitted through the internet and television, published, and transmitted to Front Groups and KOLs located across the country and Plaintiff's community;
- b. Written representations and telephone calls between the RICO Marketing Defendants and Front Groups regarding the misrepresentations, marketing statements and claims about opioids, including the non-addictive, safe use of chronic long-term pain generally;
- c. Written representations and telephone calls between the RICO Marketing Defendants and KOLs regarding the misrepresentations, marketing statements and claims about opioids, including the non-addictive, safe use of chronic long-term pain generally;
- d. E-mails, telephone and written communications between the RICO Marketing Defendants and the Front Groups agreeing to or implementing the opioids marketing scheme;

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

- e. E-mails, telephone and written communications between the RICO Marketing Defendants and the KOLs agreeing to or implementing the opioids marketing scheme;
- f. Communications between the RICO Marketing Defendants, Front Groups and the media regarding publication, drafting of treatment guidelines, and the dissemination of the same as part of the Opioid Marketing Enterprise;
- g. Communications between the RICO Marketing Defendants, KOLs and the media regarding publication, drafting of treatment guidelines, and the dissemination of the same as part of the Opioid Marketing Enterprise;
- h. Written and oral communications directed to State agencies, federal and state courts, and private insurers throughout Plaintiff's community that fraudulently misrepresented the risks and benefits of using opioids for chronic pain; and
- i. Receipts of increased profits sent through the U.S. Mail and interstate wire facilities—the wrongful proceeds of the scheme.

1240. In addition to the above-referenced predicate acts, it was intended by and foreseeable to the RICO Marketing Defendants that the Front Groups and the KOLs would distribute publications through the U.S. Mail and by interstate wire facilities, and, in those publications, claim that the benefits of using opioids for chronic pain outweighed the risks of doing so.

1241. To achieve the common goal and purpose of the Opioid Marketing Enterprise, the RICO Marketing Defendants and members of the Opioid Marketing Enterprise hid from the consumers, prescribers, regulators and the Plaintiff: (a) the fraudulent nature of the RICO Marketing Defendants' marketing scheme; (b) the fraudulent nature of statements made by the RICO Marketing Defendants and by their KOLs, Front Groups and other third parties regarding the safety and efficacy of prescription opioids; and (c) the true nature of the relationship between the members of the Opioid Marketing Enterprise.

1242. The RICO Marketing Defendants, and each member of the Opioid Marketing Enterprise agreed, with knowledge and intent, to the overall objective of the RICO Marketing

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

Defendants' fraudulent scheme and participated in the common course of conduct to commit acts of fraud and indecency in marketing prescription opioids.

1243. Indeed, for the RICO Marketing Defendants' fraudulent scheme to work, each of them had to agree to implement similar tactics regarding fraudulent marketing of prescription opioids. This conclusion is supported by the fact that the RICO Marketing Defendants each financed, supported, and worked through the same KOLs and Front Groups, and often collaborated on and mutually supported the same publications, CMEs, presentations, and prescription guidelines.

1244. The RICO Marketing Defendants' predicate acts all had the purpose of creating the opioid epidemic that substantially injured Plaintiff's business and property, while simultaneously generating billion-dollar revenue and profits for the RICO Marketing Defendants. The predicate acts were committed or caused to be committed by the RICO Marketing Defendants through their participation in the Opioid Marketing Enterprise and in furtherance of its fraudulent scheme.

B. The Opioid Supply Chain Enterprise

1245. Faced with the reality that they will now be held accountable for the consequences of the opioid epidemic they created, members of the industry resort to "a categorical denial of any criminal behavior or intent."⁵⁵⁶ Defendants' actions went far beyond what could be considered ordinary business conduct. For more than a decade, certain Defendants, the "RICO Supply Chain Defendants", Purdue, Cephalon, Endo, Mallinckrodt, Actavis (the "RICO Supply Chain Manufacturers"), along with McKesson, Cardinal Health, and AmerisourceBergen (the "RICO Supply Chain Distributors") (collectively, the "RICO Supply Chain Defendants") worked together

⁵⁵⁶ McKesson Responds to Recent 60 Minutes Story About January 2017 Settlement With the Federal Government, McKesson, <http://www.mckesson.com/about-mckesson/fighting-opioid-abuse/60-minutes-response> (last visited, Apr. 21, 2018).

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

in an illicit enterprise, engaging in conduct that was not only illegal, but in certain respects anti-competitive, with the common purpose and achievement of vastly increasing their respective profits and revenues by exponentially expanding a market that the law intended to restrict.

1246. Knowing that dangerous drugs have a limited place in our society, and that their dissemination and use must be vigilantly monitored and policed to prevent the harm that drug abuse and addiction causes to individuals, society and governments, Congress enacted the Controlled Substances Act (“CSA”). Specifically, through the CSA, which created a closed system of distribution for controlled substances, Congress established an enterprise for good. The CSA imposes a reporting duty that cuts across company lines. Regulations adopted under the CSA require that companies who are entrusted with permission to operate within this system cannot simply operate as competitive in an “anything goes” profit-maximizing market. Instead, the statute tasks them to watch over each other with a careful eye for suspicious activity. Driven by greed, Defendants betrayed that trust and subverted the constraints of the CSA’s closed system to conduct their own enterprise for evil.

1247. As “registrants” under the CSA, the RICO Supply Chain Defendants are duty bound to identify and report “orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.”⁵⁵⁷ Critically, these Defendants’ responsibilities do not end with the products they manufacture or distribute -- there is no such limitation in the law because their duties cut across company lines. Thus, when these Defendants obtain information about the sales and distribution of other companies’ opioid products, as they did through data mining companies like IMS Health, they were legally obligated to report that activity to the DEA.

⁵⁵⁷ 21 C.F.R. 1301.74(b).

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

1248. If morality and the law did not suffice, competition dictates that the RICO Supply Chain Defendants would turn in their rivals when they had reason to suspect suspicious activity. Indeed, if a manufacturer or distributor could gain market share by reporting a competitor's illegal behavior (causing it to lose a license to operate, or otherwise inhibit its activity), ordinary business conduct dictates that it would do so. Under the CSA this whistleblower or watchdog function is not only a protected choice, but a statutory mandate. Unfortunately, however, that is not what happened. Instead, knowing that investigations into potential diversion would only lead to shrinking markets. The RICO Supply Chain Defendants elected to operate in a conspiracy of silence, in violation of both the CSA and RICO.

1249. The Opioid Supply Chain Enterprise is an association in fact enterprise that began in the mid-90s and developed over the ensuing years to grow into a tightly knit network of billion-dollar companies profiting from branded and generic opioid sales. The formation and existence of the Opioid Supply Chain Enterprise was originally facilitated by direct interactions between the RICO Supply Chain Defendants' employees. As the Opioid Supply Chain Enterprise grew, the RICO Supply Chain Defendants eventually incorporated other resources that allowed them to deepen their relationships and coordinated efforts to avoid DEA scrutiny and minimize their regulatory obligations. Some of these additional resources, like the Healthcare Distribution Alliance (together with its predecessors,⁵⁵⁸ the "HDA") were formally organized businesses that existed separate and apart from the Opioid Supply Chain Enterprise, but were controlled by the RICO Supply Chain Defendants (through their membership on the Board of Directors and Executive Committee, and substantial financial contributions) to achieve the common purpose of

⁵⁵⁸ The Healthcare Distribution Alliance was formerly known as Healthcare Distribution Management Association (HDMA), which was formerly known as National Wholesale Druggists' Association (NWDA), which was formerly known as Western Wholesale Druggists' Association (WWDA)

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

the Opioid Supply Chain Enterprise. Other resources, like the Pain Care Forum (“PCF”), the New Jersey Pharmaceutical Industry Working Group (“NJPIG”), and the Anti-Diversion Industry Working Group (“ADIWG”), were informal associations created by the RICO Supply Chain Defendants. Specifically, these groups were developed to serve the RICO Supply Chain Defendants’ mutual interests, allowing them to coordinate their efforts.

1250. HDA is of particular importance to the RICO Enterprise. HDA (through its predecessor entities) was initially formed in 1876 to “remedy the existing evils in the wholesale drug business, and enable the merchants to carry on business on a more profitable basis.” It has strayed from its mission and now serves as a powerful tool for the distributor industry to influence the media, the marketplace, state and federal regulators and elections across the country.

1251. Now headquartered in Arlington, Virginia, HDA represents 36 distribution companies — national, regional and specialty — as well as more than 130 manufacturer and more than 50 service provider/international members, respectively. These members serve more than 200,000 licensed healthcare providers, delivering over 15 million products to these outlets every day. Just as in 1876, HDA’s stated mission has remained the same: to protect patient safety and access to medicines through safe and efficient distribution; to advocate for standards, public policies and business processes that enhance the safety, efficiency and value of the healthcare supply chain; and to create and exchange industry knowledge and best practices.

1252. HDA is controlled by an Executive Committee which, for all time relevant, included the Big Three Distribution Defendants in this action: Cardinal Health, AmerisourceBergen and McKesson. No decision is made at HDA without the blessing and endorsement of the Big Three Distributors.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

1253. The first nexus of communication that leads to the formation of the Opioid Supply Chain Enterprise begins in the mid-90s when Purdue and the RICO Supply Chain Distributors began working together on their approach to suspicious order monitoring and the release of Oxycontin. As Purdue wrote, its relationship with the top four wholesalers was very solid. Purdue's contacts facilitated effortless movement through the RICO Distributor organization. Purdue explained that with wholesaler friendly policies, Purdue could expect programs that were friendly and profitable for Purdue

1254. Then, beginning in the early 2000s, the RICO Supply Chain Manufacturers also began working together to protect their interests. Specifically, Purdue reached out to Cephalon to discuss organizing and meeting with other manufacturers, including Endo and Johnson & Johnson. Purdue's suggestion served as the jumping off point that led to quarterly meetings in 2004 to discuss public policy issues surrounding pain management, controlled substances, and diversion, abuse and misuse of our products. This group eventually became known as the PCF and its membership included all of the RICO Supply Chain Manufacturers, two of the RICO Supply Chain Distributors, and the HDA (as directed by its RICO Distributor members).

1255. The DEA's increased enforcement in the mid-2000s led to a significant increase in communication between the RICO Supply Chain Defendants, and in their work with the HDA, PCF, NJPIG and ADIWG, all of which was being conducted to further the goal of unlawfully selling opioids. In 2005/2006, the DEA conducted its "Distributor Initiative," which included DEA meetings with registrants, and conferences where DEA explained suspicious order monitoring requirements, which are part of the larger statutory duty to prevent diversion. The DEA also issued three letters (the "Dear Registrant Letters") as part of the initiative. Finally, in 2007, the DEA issued its first immediate suspension order or "ISO" that suspended

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

AmerisourceBergen's registration to dispense controlled substances from its Lakeland, Florida distribution center. The suspension of AmerisourceBergen's registration effectively stopped its ability to profit from the distribution of controlled substances during the height of the diversion epidemic in Florida and, most importantly, sent shockwaves through the supply chain industry.

1256. As documents produced from the HDA indicate, the supply chain industry was concerned about "the intensity and impact of the Drug Enforcement Administration's recent actions" in 2007.⁵⁵⁹ As a result, there is a significant increase in communication between the RICO Supply Chain Defendants, as well as the participation in the HDA, PCF, NJPIG, and ADIWG, and interaction between the HDA and PCF. Among other things, one goal was to "develop a comprehensive DEA strategy."⁵⁶⁰ As Purdue noted, collaboration between manufacturers and distributors was critical. "The manufacturer engaging in a collaborative, as needed effort with the distributor" results in the "benefit and protection of each."⁵⁶¹ Purdue concluded that the distributors must "pledge to remain in close contact with each other whenever there may be a questionable order" in order to "protect ourselves and our registrations regarding suspicious order discovery and reporting."⁵⁶² And, the protection referred to by Purdue, was specifically related to protecting the continued shipment of its drugs to customers:

1257. We really do have to partner with our own customers to help them in their business with pharmacies catering to "pain clinics". Otherwise, [distributors] will cut [the pain clinics] off based on some kind of threshold. We need to convince [distributors that] they should talk to us

⁵⁵⁹ CAH_MDL_PRIORPROD_DEA07_00877471

⁵⁶⁰ *Id.*

⁵⁶¹ PPLPC053000021255 at 53000021258.

⁵⁶² *Id.* at 53000021257.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

when our product is involved and make it a joint decision, etc. just as we need to consult with them from our end.⁵⁶³

1258. Aside from the direct interactions between Purdue and the RICO Supply Chain Distributors, the RICO Supply Chain Manufacturers were directly interacting with each other through the PCF and through direct meetings about their suspicious order monitoring policies and procedure. The RICO Supply Chain Manufacturers helped each other to develop suspicious order monitoring policies and procedures beginning in the time period after 2010. These systems were, in large part, modeled after and based on input and feedback from Purdue, and there was a substantial amount of collaboration between the RICO Supply Chain Manufacturers about how to set up their system, including the best way to receive and utilize chargeback data from the RICO Supply Chain Distributors in order to identify suspicious orders. On the part of the RICO Supply Chain Distributors, there were frequent communications between the RICO Supply Chain Distributors employees regarding their approach to suspicious order monitoring. While much of this interaction happened through meetings and phone calls of the HDA, there is also evidence that these employees considered their counterparts to be close or good friends, and that the RICO Supply Chain Distributors had “huddles”⁵⁶⁴ before, during, and after HDA conferences where they discussed suspicious order monitoring and admitted that they were not reporting suspicious orders because there was no upside to it.

1259. The RICO Supply Chain Defendants’ scheme required the participation of all. If any one-member broke rank, its compliance activities would highlight deficiencies of the others, and the artificially high quotas they maintained through their scheme would crumble. But, if all

⁵⁶³ PPLPC018000200323 at 18000200324.

⁵⁶⁴ MCKMDL00545341 at 00545432.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

the members of the Opioid Supply Chain Enterprise conducted themselves in the same manner, it would be difficult for the DEA to go after any one of them.

1260. In addition to direct meetings, communications, and interactions of the RICO Supply Chain Defendants, further collaboration and relationship formation occurred through the activities of and participation in the HDA, PCF, NJPIG, and ADIWG. These groups were centrally important in the RICO Supply Chain Defendants' efforts to counter the DEA's attempts to enforce the suspicious order monitoring provisions of the CSA. Accordingly, through the connections they made as a result of their participation in these groups, the RICO Supply Chain Defendants chose to flout the closed system designed to protect the citizens. Through their work with the HAD in particular, the RICO Supply Chain Distributors were able to formulate a comprehensive and joint DEA strategy in response to the suspension of AmerisourceBergen's registration and the subsequent suspensions of the McKesson and Cardinal Health registrations. The strategy began with scheduling meetings with the DEA to provide the HDA's members the ability to claim they were doing something to combat diversion. These strategy meetings led to the recommendation from Cardinal Health's current lawyers (Williams & Connolly) that the HDA should develop a set of Industry Compliance Guidelines ("ICGs") for complying with the suspicious order monitoring obligations under the CSA.

1261. The ICGs are important for a number of reasons. First, the HDA worked extremely closely with its members to draft the ICGs, including obtaining copies of its members' suspicious order monitoring policies and procedures, and interview its members employees about the members' practices. Eventually, the ICGs were ratified by the Executive Committee of the HDA reflecting an agreement among at least the RICO Supply Chain Distributors to a course of conduct that should have been utilized as a basis for complying with the CSA that was achieved by

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

reviewing and sharing suspicious order monitoring policies and procedures. Second, the HDA worked extremely closely with DEA, including receiving detailed comments and suggestions about what must be included in the ICGs. As such, HDA and its members were aware of very specific guidance from the DEA about what was required to comply with the CSA. Third, during the drafting of the ICGs, the HDA represented to the DEA that it would work with HDA members to ensure that they implemented the ICGs as part of the HDA's commitment to protecting patient safety. Nevertheless, the HDA was on actual notice before it made that representation, received directly from AmerisourceBergen, that the RICO Supply Chain Distributors did not intend to implement the ICGs. As such, the ICGs represent an actual misrepresentation that was transmitted to the DEA at the direction of its members—the RICO Supply Chain Distributors—that supports an allegation of mail/wire fraud. Finally, the HDA represented to the DEA that they would work with other supply chain industry stakeholders like the PCF, and other trade associations' manufacturers and pharmacists, to help their members implement the ICGs. Moreover, the HDA presented to members of the PCF about the ICGs in order to educate them about the efforts HDA was undertaking in that regard.

1262. Put simply, the store of the HDA's work on the ICGs is extremely strong evidence of the formation of the Opioid Supply Chain Enterprise, its common purpose, and that it engaged in racketeering activity to accomplish that common purpose. Notably, the HDA publicly represented to the DEA that HDA hoped “that DEA would find the guidelines acceptable as a voluntary ‘consent decrees,’” but “did not expect these guidelines to result in weakening DEA’s enforcement prerogatives.”⁵⁶⁵ Yet, in private conversations with its members, HDA admitted that the “Purpose of ICG and DEA Communications” was to ““Head-off” further enforcement or

⁵⁶⁵ CAH_MDL2804_02489188

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

regulatory action.”⁵⁶⁶ Further evidence of the Opioid Supply Chain Enterprise’s common purpose related to the ICGs occurred in 2012 when the ICGs were relied on by the DEA in a regulatory enforcement action against Walgreens. After the HDA learned of this information, the Executive Committee instructed HDA to immediately take the ICGs off of the HDA’s website because they were never meant to be used as an industry standard to be used against companies in the pharmaceutical supply chain.⁵⁶⁷ This action by the HDA is particularly indicative of the common purpose of the Opioid Supply Chain Enterprise because when the HDA originally presented the ICGs to the DEA and analogized them to a similar situation “where a set of voluntary standard were reviewed by FDA and eventually became a standard practice.”⁵⁶⁸ But when the HDA pulled the ICGs from the website in 2013 they internally discussed that the “guidelines were never intended to constitute a standard” so “they [were] taken down from the HDMA website, at the direction of the [Government & Public Policy Council]” of the HDA.⁵⁶⁹

1263. Publicly, in 2008, they announced their formulation of “Industry Compliance Guidelines: Reporting Suspicious Orders and Prevention Diversion of Controlled Substances.” But, privately, the RICO Supply Chain Defendants refused to act and through their lobbying efforts, they collectively sought to undermine the impact of the CSA. Indeed, despite the issuance of these Industry Compliance Guidelines, which recognize these Defendants’ duties under the law, as illustrated by the subsequent industry-wide enforcement actions and consent orders issued after that time, none of them complied. John Gray, President and CEO of the HDA said to Congress in 2014, it is “difficult to find the right balance between proactive anti-diversion efforts while not inadvertently limiting access to appropriately prescribed and dispensed medications.” Yet, the

⁵⁶⁶ HDA_MDL_000145918 at 000145032.

⁵⁶⁷ HDA_MDL_000080421; HDA_MDL_000155930 at 000155936.

⁵⁶⁸ CAH_MDL2804_02489188 at 02489189.

⁵⁶⁹ HDA_MDL_000155930 at 000155936.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

RICO Supply Chain Defendants apparently all found the same profit-maximizing balance -- intentionally remaining silent to ensure the largest possible financial return.

1264. Aside from the ICGs, the RICO Supply Chain Distributors used the HDA to accomplish other Enterprise goals. Most of these were driven directly by the RICO Supply Chain Distributors, but it should not be forgotten that the HDA services manufacturer members as well and that it dedicates an entire council and multiple committees to servicing manufacturer members, including all of the RICO Supply Chain Manufacturers, in their businesses and interests. Further actions by the HDA that served the interests of the Opioid Supply Chain Enterprise included lobbying in favor of issues that undermined DEA and its attempts to enforce the CSA, including by negatively portraying the DEA in the HDA's discussions with the Government Accountability Office.

1265. The efforts of the HDA to combat the regulatory obligations and enforcement authority of the DEA have continued to this day.

1266. In December 2011, HDA met with the DEA to discuss DEA's actions against Cardinal and CVS.⁵⁷⁰ On February 16, 2012, the HDA Executive Committee met at The Lodge of Pebble Beach in Pebble Beach, California⁵⁷¹ wherein the decision was made to retain outside counsel to draft an amicus brief in *Cardinal Health, Inc. v. Holder*, 846 F. Supp. 2d 203 (D.D.C. 2012).⁵⁷² HDA advised the federal court, as required by Fed. R. App. P. 29(c)(5), that no party's counsel authored the HDA brief "in whole or in part." Nonetheless, internal communications reveal that Cardinal Health's counsel pre-viewed, edited and offered amendments to the brief.⁵⁷³ The amicus brief served as the statement of the industry mantra: Blame the DEA.

⁵⁷⁰ HDA_MDL_000019845.

⁵⁷¹ HDA_MDL_000020020.

⁵⁷² HDA_MDL_000019845; ABDCMDL00266101; HDA_MDL_000218844.

⁵⁷³ HDA_MDL_000218844.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

1267. On April 6, 2012, an Executive Committee Conference call was conducted to “address recent activity with respect to suspicious order monitoring and the role of healthcare distributors. HDA has testified before Congress and prepared an amicus curiae brief for filing with the federal Court of Appeals in the Cardinal v. Holder litigation.” Chairman Moody (Mutual Wholesale Drug Company) and Vice Chairman Neu (ABDC) “expressed concern about the trend of recent developments” and thought it time for the Executive Committee to review recent events and “plot a course for going forward.”⁵⁷⁴

1268. On June 10, 2012, the HDA Executive Committee met at JW Marriott San Antonio Hill Country in San Antonio, Texas⁵⁷⁵ wherein HDA confirmed it “filed an amicus curiae brief in support of Cardinal Health's position before the Federal Court of Appeals for the District of Columbia Circuit. Cardinal subsequently reached a settlement with DEA and withdrew its appeal. The DEA administrative proceeding was terminated; Cardinal Health agreed to a two-year suspension of its Lakeland facility registration and some enhanced regulatory oversight by DEA.” Mr. Mike Kaufmann (Pharmaceutical Segment, Cardinal Health, Inc.) thanked the Executive Committee members and HDA for its support during its litigation with DEA.

1269. On September 30, 2012, the HDA Executive Committee met at The Ritz Carlton Palm Beach in Manalapan, Florida⁵⁷⁶ wherein the recently filed “West Virginia Lawsuit” was discussed. West Virginia Attorney General Darrell McGraw filed suit against 14 out-of-state drug distributors alleging violations of the State Controlled Substances Act and Consumer Credit and Protection Act for their roles in allegedly supplying controlled substances to state “pill mills.” Mr. John Parker (HDA Vice President, Communications) presented an update on the current state of

⁵⁷⁴ HDA_MDL_000020027.

⁵⁷⁵ HDA_MDL_000020030

⁵⁷⁶ HDA_MDL_000020036.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

play regarding how wholesalers are being portrayed in the media and their implications for HDA members. The Executive Committee voted to develop a public relations program. Shortly thereafter, the HDA “approved the selection of APCO Worldwide to partner with HDMA and its member companies on the development of a communications strategy to address the issue of prescription drug abuse and diversion.”⁵⁷⁷

1270. On November 16, 2012, an Executive Committee Conference call was conducted⁵⁷⁸ wherein President Gray drew the Executive Board's attention to the November 16, 2012 edition of the Wall Street Journal, which had a story about DEA bringing actions against FedEx and UPS with respect to controlled substances. He noted that DEA's efforts have broadened the initiative and created potential allies for HDA and its members. Mr. John Parker (HDA Vice President, Communications) discussed the Phase I proposal of APCO's COMMUNICATIONS INITIATIVE ON PRESCRIPTION DRUG ABUSE AND DIVERSION including a strategic communications effort to address prescription drug abuse and diversion with a focus on the contributions made by distributors. APCO proposed qualitative and quantitative research designed to arm HDA with the appropriate resources to identify threats, mitigate risks, educate primary stakeholders and build the foundation for a leadership platform. The research phase would last approximately three months with findings to be shared with the Executive Committee at its next meeting on February 22, 2013.

1271. On December 14, 2012, an Executive Committee Conference call was conducted⁵⁷⁹ to address two principal topics: (1) interest in and need for HDA participation in established or ad hoc organizations designed to expand and deepen the voice of pharmacy stakeholders in public

⁵⁷⁷ HDA_MDL_000217059_R.

⁵⁷⁸ HDA_MDL_000020042.

⁵⁷⁹ HDA_MDL_000020046

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

policy debates; and (2) potential expansion of HDA membership to include members such as Express Scripts.

1272. One of the most startling examples of the HDA's work and its commitment to helping its members avoid regulatory compliance occurred in 2012 just after Cardinal Health had its registration suspended for a second time. After the suspension, HDA convened a meeting with the same Williams & Connolly lawyers, during which the HDA and its members were advised that if they really wanted to avoid further DEA enforcement, then they were better off improving their regulatory compliance.⁵⁸⁰ Instead of adopting this suggestion, the notes from that meeting indicate that a myriad of strategies were discussed, and later implemented, to help HDA members avoid enforcement without improving their regulatory compliance.

1273. Further evidence of the existence of the Opioid Supply Chain Enterprise, can be found in the PCF and its interactions with the HDA, and in the formation of the NJPIG and ADIWG. The HDA's work with the PCF primarily focused on Purdue and its requests that the HDA support PCF-related initiatives. Aside from educating the PCF on the ICGs that the HDA drafted, HDA worked with the PCF on Risk Evaluation and Mitigation Strategy ("REMS") guidelines for prescription opioids, hydrocodone rescheduling, and a deep level of coordination for the Marino Blackburn Bill, also known as S.483 ("Bill").

1274. Beginning in 2013, Defendant HDA and other stakeholder organization began working with Representatives Tom Marino (R-PA) and Marsha Blackburn (R-TN) to draft legislation which was formally introduced on February 21, 2014, as H.R. 4069 as Ensuring Patient Access and Effective Drug Enforcement Act. HDA and the Big3 Distributors intended the Marino Bill to "tie the hands" of the DEA to actively and aggressively address diversion and compliance

⁵⁸⁰ HDA_MDL_000215234 at 000215235.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

with the CSA.”⁵⁸¹ The Bill effectively removed the DEA’s ability to issue immediate suspension orders regarding manufacturer or distributor registrations.

1275. While HDA was lobbying in favor of the Bill, it was advised that the DEA was categorically opposed to the Bill because it would tie the DEA’s hands and prevent the DEA from enforcing the CSA to prevent diversion.⁵⁸² HDA was instructed by the RICO Supply Chain Distributors to pass the Bill despite knowing DEA’s stance and the Bill that was eventually signed into law contained all of the provisions that the DEA expressed concern about.⁵⁸³ Prior to the final passage of the Bill, there was some concern between the HDA, RICO Supply Chain Distributors and Manufacturers about the final language of the Bill. The communications between HDA and Purdue on behalf of the PCF increased significantly during that time period and resulted in language that the two groups agreed on, and the eventual passage of the Bill. After the Marino Blackburn Bill passed, HDA employees wrote to the PCF, thanked PCF members for their support, and represented that they could not have passed the Bill without the mutual support of the PCF members. The importance of the PCF in addition to the HDA cannot be understated. As another example, the PCF was so important that AmerisourceBergen considered joining directly, and McKesson did, in fact join directly. HDA’s membership in the PCF continued through January 2017, and to this day the HDA still requested the opportunity to receive emails and participate in discussions, meetings, etc.

1276. The NJPIG and ADIWG working groups are but two examples of the many working groups that were formed by the RICO Supply Chain Defendants. These smaller entities

⁵⁸¹ HDA_MDL_000035893.

⁵⁸² MCKMDL00651560 at 00651561.

⁵⁸³ HDA_MDL_000155930 at 000155941 (“President Gray noted that the HDMA Executive Committee had discussed and agreed to prioritize objectives on prescription drug abuse in the following order: 1.) exhaust all efforts to secure passage of S.483”).

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

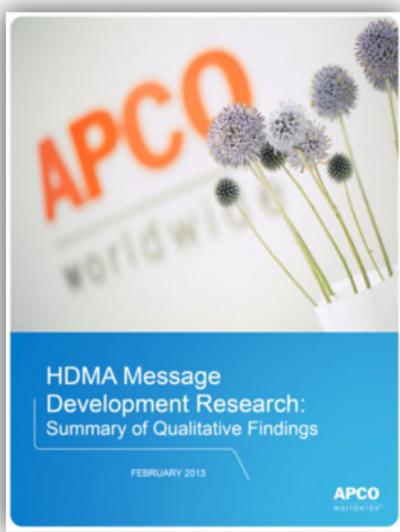
were created for the specific purpose of allowing member companies, including the RICO Supply Chain Defendants, to coordinate on issues that affected them in specific regions and on specific topics. The NJPIG, for example, was started by Purdue allegedly at the suggestion of the DEA in 2008. The ADIWG was formed by Mallinckrodt in 2013 (one year after Mallinckrodt's registration was suspended in 2012). Finally, a third entity that was not as active as either the NJPIG or the ADIWG is the Midwest Compliance Discussion Group ("MDWG") was formed in 2008, in response to the DEA's "Dear Registrant" letters. These informal groups, membership in which included mixtures of RICO Supply Chain Manufacturers and RICO Supply Chain Distributors, were used by the members to approach the DEA for the purposes of giving them cover with the DEA, *i.e.* doing something in relation to their obligation to identify and report suspicious orders. The formation of these entities is in some ways stronger evidence of the existence of the Opioid Supply Chain Enterprise, than what they did because it shows another layer of relationships among the RICO Supply Chain Defendants who were already active in the HDA and the HDA.

1277. On February 22, 2013, the HDA Executive Committee met at The Four Seasons Hotel in Washington, D.C.,⁵⁸⁴ wherein the "State of West Virginia Lawsuit" was discussed: Former West Virginia Attorney General Darrell McGraw sued 14 out-of-state drug distributors alleging violations of the state Controlled Substances Act and Consumer Credit and Protection Act

⁵⁸⁴ HDA_MDL_000020049

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

for their roles in allegedly supplying controlled substances to state "pill mills." At this same meeting, John Parker (HDA Vice President, Communications) provided a brief background on Phase 1 of the public relations project and the selection of APCO to be the public relations partner.



Mr. Michael Tuffin (Managing Director, Washington, DC, APCO Worldwide) introduced the work to date, which involved mostly research of opinion leaders and views of thought leaders about the problem of controlled substance diversion and abuse and the roles played by doctors, clinics, distributors, manufacturers and government.⁵⁸⁵ APCO conducted a series of focus groups and interviews, looking at who opinion leaders blame for drug abuse and diversion and possible solutions. Importantly, the focus group revealed that "Without access to data, respondents question how distributors can be held responsible."⁵⁸⁶ The Executive Committee voted to approve the continuation of the project - complete Phase I and initiate a Phase II that builds on the stakeholder research findings and key messages.⁵⁸⁷

1278. On April 25, 2013, the HDA distributed its Crisis Playbook: An Interactive Guide to Crisis Communications⁵⁸⁸ to the Executive Committee and Board of Directors (including

⁵⁸⁵ HDA_MDL_000031703.

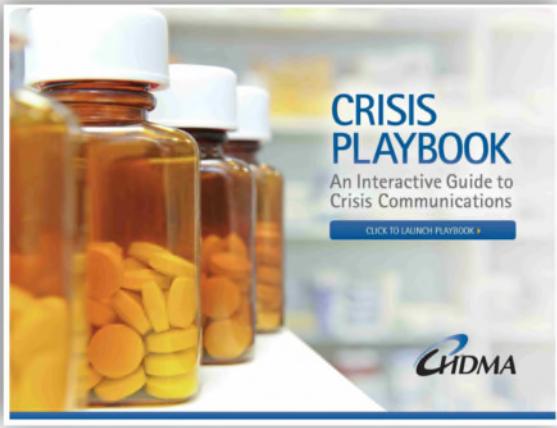
⁵⁸⁶ HDA_MDL_000031775.

⁵⁸⁷ HDA_MDL_000217059_R

⁵⁸⁸ HDA_MDL_000072090

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

Cardinal Health, McKesson and AmerisourceBergen).⁵⁸⁹ The 44 page playbook identified the



objective of providing clear guidelines for classifying crisis situations, defining roles and responsibilities in a crisis situation, creating an easy-to-use, step-by-step crisis response protocol and having ready-to-use materials on hand for risk situations. The playbook set forth several “Diversion Issues Scenarios” including

instructions on how to respond to a DEA registration suspension. In what would prove to be a prophetic reflection of a future propaganda campaign, the playbook rhetorically asks: “Does this present an opportunity for HDMA to proactively push its message of misdirected DEA enforcement with national media?” Similar playbook protocols are set forth for diversion lawsuits and a Congressional inquiry. The playbook was approved and authorized by the HDA Executive Committee which included senior management from Cardinal Health, McKesson and AmerisourceBergen.

1279. On June 2, 2013, the HDA Executive Committee and Board of Directors met at J.W. Marriott Orlando, Grande Lakes Orlando, FL.⁵⁹⁰ wherein APCO presented HDMA-APCO Stakeholders Research and External Positioning Project.⁵⁹¹ The study concluded that primary distributors rank very low on the "who's to blame" list for prescription drug diversion and misuse and recommended a targeted communications strategy. The report highlights a comment from an “opinion leader” regarding distributor liability: “That’s crazy. It’s like they’re suing the

⁵⁸⁹ HDA_MDL_000217059_R.

⁵⁹⁰ HDA_MDL_000020057

⁵⁹¹ HDA_MDL_000031691

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

distributors for people's prescription drug abuse. That's like suing McDonald's for people's cholesterol problems."⁵⁹²

1280. On September 29, 2013, the HDA Executive Committee and Board of Directors met at The Greenbrier in White Sulphur Springs, West Virginia.⁵⁹³ Mr. Patrick Kelly (HDA Senior Vice President, Government Affairs) provided an update on the Marino Bill "which addresses/advances HDA interests." The Marino Bill permitted a non-compliant registrant an opportunity to cure before the DEA could take punitive action and changed the standard upon which revocation occurred. In essence, the Marino Bill removed the most effective deterrent and neutered DEA enforcement actions. The Minutes record that "HDMA members continue to have difficulty with DEA inspections/audits due, in large part, to not knowing what is required of the distributor to address suspicious orders."⁵⁹⁴ In addition, HDA decided to take down its industry compliance guidelines on suspicious orders from the HDA website out of fear the DEA would use it as "an industry standard."⁵⁹⁵

1281. On February 27, 2014, the HDA Executive Committee met at The Ritz-Carlton Tysons Corner in McLean, VA, just outside Washington DC.⁵⁹⁶ The primary purpose of the meeting was to identify additional sponsors for the Marino Bill and address the "lack of clarity in DEA's current enforcement scheme." On motion duly made and seconded, the Executive Committee allocated up to \$250,000 to be taken from reserves to hire a lobbyist to support the Marino Bill.

⁵⁹² *Id.*

⁵⁹³ HDA_MDL_000020063.

⁵⁹⁴ HDA_MDL_000019851.

⁵⁹⁵ HDA_MDL_000019851.

⁵⁹⁶ HDA_MDL_000020063.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

1282. On September 28, 2014, the HDA Executive Meeting met at The Montage Laguna Beach in Laguna Beach, California.⁵⁹⁷ The Executive Committee discussed the passage of the Marino Bill by the House of Representatives and noted that Representatives Blackburn (R-TN) and Marino (R-PA) sent a letter to the Department of Justice seeking an investigation into inflammatory remarks made by DEA Deputy Administrator Rannazzisi. HDA acknowledged it continues to work cooperatively with the Alliance to Prevent the Abuse of Medicines as well as the Pain Care Forum.

1283. On June 7, 2015, the HDA Executive Committee met at the JW Marriott San Antonio Hill Country in San Antonio, Texas.⁵⁹⁸ Mr. Gray and Mr. John Parker (HDMA Senior Vice President, Communications) provided background on litigation in West Virginia filed in 2012 against 13 distributors, 11 of whom are HDMA members. In essence, the lawsuit alleges that those distributors are improperly supplying controlled substances to West Virginia "pill mills," to the detriment of the state and legitimate patients who need controlled substances. HDA reported to the Executive Committee that "recent media reports have insinuated that distributors are responsible for controlled substance problems in West Virginia, including unlawful diversion and increased difficulty in getting controlled substances for legitimate uses." Following discussion, there was general agreement that HDA needs to engage the media including taking a strong, visible role in the passage of the Marino Bill by the Senate, engaging in proactive and reactive media outreach with other stakeholders in West Virginia to offer deep background briefings, convening a public/private summit to address relevant issues with key stakeholders and reaching out to Sen. Manchin and staff.

⁵⁹⁷ HDA_MDL_000020084.

⁵⁹⁸ HDA_MDL_000020094.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

1284. On February 18, 2016, the HDA Executive Committee met at The Lodge at Pebble Beach in Pebble Beach, California.⁵⁹⁹ HDA Vice Chairman Jon Giacomin (Cardinal Health, Inc.) chaired the meeting. In attendance was Robert Mauch (President, AmerisourceBergen Drug Corporation) and Mark Walchirk (President, US Pharmaceutical, McKesson Corporation). The meeting concluded that “the series of DEA and state actions as efforts to improperly expand distributors’ responsibilities beyond simply reporting suspicious orders to actually preventing the distribution of controlled substances to licensed dispensers.” The decision was made to file an amicus brief in the *Masters* case with a “central theme” that “DEA must follow statutory and regulatory requirements regarding the imposition of suspicious order reporting notice-and-comment rulemaking required.” The intention of the brief was to “place the role and capabilities of the distributor in context, noting that distributors neither prescribe, nor dispense controlled substances, and therefore are in no position to adjudicate the legitimacy of an order.” On motion duly made and seconded, the Executive Committee unanimously approved filing of an amicus curiae brief subject to final review and approval of the brief. The amicus brief argues: “[T]here is no prohibition on shipment of suspicious orders.”

1285. On June 12, 2016, the HDA Executive Committee met at The Broadmoor in Colorado Springs, Colorado.⁶⁰⁰ Following a brief introduction by President and CEO John Gray, Ms. Elizabeth Gallenagh (Senior Vice President, Government Affairs and General Counsel) and Mr. John Parker (Senior Vice President, Communications) led a discussion on whether and how HDA should be prepared to respond to negative media impact and misinformation regarding the role of drug distributors in the abuse of prescription opioids, whether in connection with ongoing West Virginia litigation or possible similar litigation in other states.

⁵⁹⁹ HDA_MDL_000020104.

⁶⁰⁰ HDA_MDL_000020110.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

1286. On February 22, 2017, the HDA Executive Committee met at The Lodge at Pebble Beach Pebble Beach, CA.⁶⁰¹ An update was provided the “highly inflammatory media environment” regarding the role of wholesalers as well as the cases that have been brought in West Virginia. Mr. Robert Schooling (Reservoir Communications Group) discussed a proposal for the development and roll-out of a six-month Communications Program, explaining the role, in appropriate context, of the distributor. On motion duly made and seconded, \$240,000 was approved for a six-month engagement of Reservoir Communications Group for message development and communications strategy. The RICO Supply Chain Defendants continue to operate through HDA in an effort to effect their enterprise to this day.

1287. The sheer volume of prescription opioids flooding out of the doors of the RICO Supply Chain Defendants and into communities across the country, including the Plaintiffs’ Community, shocks the conscience and required each RICO Supply Chain Defendants to take appropriate action, such as investigating and reporting the orders as suspicious. Given their place in the supply chain, the RICO Supply Chain Defendants are uniquely situated to identify suspicious transactions. However, determined to increase their revenues, each of the RICO Supply Chain Defendants willfully ignored obvious warning signs concerning suspicious orders. It would be virtually impossible for all of the orders to be legitimate, as there was no medical-need correlation justifying the skyrocketing orders for these addictive drugs.

1288. As described above, at all relevant times, the RICO Supply Chain Defendants operated as an association-in-fact enterprise formed for the purpose of unlawfully increasing sales, revenues and profits by fraudulently increasing the quotas set by the DEA that would allow them to collectively benefit from a greater pool of prescription opioids to manufacture and distribute.

⁶⁰¹ HDA_MDL_000020118.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

In support of this common purpose and fraudulent scheme, the RICO Supply Chain Defendants jointly agreed to disregard their statutory duties to identify, investigate, halt and report suspicious orders of opioids and diversion of their drugs into the illicit market so that those orders would not result in a decrease, or prevent an increase in, the necessary quotas.

1289. At all relevant times, as described above, the RICO Supply Chain Defendants exerted control over, conducted and/or participated in the Opioid Supply Chain Enterprise by fraudulently claiming that they were complying with their duties under the CSA to identify, investigate and report suspicious orders of opioids in order to prevent diversion of those highly addictive substances into the illicit market, and to halt such unlawful sales, so as to increase production quotas and generate unlawful profits, as follows:

1290. The RICO Supply Chain Defendants disseminated false and misleading statements to state and federal regulators claiming that:

- a. the quotas for prescription opioids should be increased;
- b. they were complying with their obligations to maintain effective controls against diversion of their prescription opioids;
- c. they were complying with their obligations to design and operate a system to disclose to the registrant suspicious orders of their prescription opioids;
- d. they were complying with their obligation to notify the DEA of any suspicious orders or diversion of their prescription opioids; and
- e. they did not have the capability to identify suspicious orders of controlled substances.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

1291. During the relevant time period, each RICO Supply Chain Defendant exerted control over its Opioid Supply Chain Enterprise and participated in the operation and management of the affairs of its Opioid Supply Chain Enterprise, directly or indirectly, in the following ways:

1292. RICO Supply Chain Defendants each obtained a license from the State Board of Pharmacy but, contrary to the requirements of State law, including federal laws incorporated by reference into State law, RICO Supply Chain Defendants failed to take necessary action to prevent the diversion of dangerously addictive prescription opioids, and in dereliction of non-delegable duties, sold opioid pills to their retail pharmacy customers notwithstanding that the increase and quantum of addictive drug orders raised serious red flags regarding the drugs' unlawful, non-medical use;

1293. RICO Supply Chain Defendants misrepresented their compliance with their legal obligations, making false assurances that their distribution complied with the law, including without limitation the requirements of an State distributor license, when, in truth, RICO Supply Chain sold all the opioids they could, for profit, and in violation of their legal duties to guard against diversion of the pills for illicit purposes;

1294. RICO Supply Chain Defendants refused to heed the DEA's warnings and continued to sell diverted opioids;

1295. RICO Supply Chain Defendants refused to abide by the terms of DEA enforcement actions and settlements, continuing to sell diverted opioids;

1296. RICO Supply Chain Defendants did not monitor, detect, investigate, refuse and report suspicious orders to the State Board of Pharmacy as required under the terms of their licenses and applicable law;

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

1297. RICO Supply Chain Defendants intentionally sold the opioids unlawfully, purely for profit and without regard to the opioid plague, notwithstanding RICO Supply Chain Defendants' knowledge that substantial foreseeable harm would occur;

1298. RICO Supply Chain Defendants only succeeded in these opioid sales by using wire and mail to communicate with the retail pharmacies.

1299. The retail pharmacies participated in each RICO Supply Chain Defendant's Supply Chain Enterprise by employing mail and wire to send orders of opioids to RICO Supply Chain Defendants and to buy opioids from RICO Supply Chain Defendants. The retail pharmacies also participated in each Defendant's RICO Supply Chain Enterprise by engaging with Defendants in violation of State drug law, as described herein.

1300. The Defendants applied political and other pressure on the DOJ and DEA to halt prosecutions for failure to report suspicious orders of prescription opioids and lobbied Congress to strip the DEA of its ability to immediately suspend registrations pending investigation by passing the "Ensuring Patient Access and Effective Drug Enforcement Act."⁶⁰²

1301. The CSA and the Code of Federal Regulations require the RICO Supply Chain Defendants to make reports to the DEA of any suspicious orders identified through the design and operation of their system to disclose suspicious orders. The failure to make reports as required by the CSA and Code of Federal Regulations amounts to a criminal violation of the statute.

⁶⁰² See HDMA is Now the Healthcare Distribution Alliance, Pharmaceutical Commerce, (June 13, 2016, updated July 6, 2016), <http://pharmaceuticalcommerce.com/business-and-finance/hdma-now-healthcare-distribution-alliance/>; Lenny Bernstein & Scott Higham, *Investigation: The DEA Slowed Enforcement While the Opioid Epidemic Grew Out of Control*, Wash. Post, Oct. 22, 2016, https://www.washingtonpost.com/investigations/the-dea-slowed-enforcement-while-the-opioid-epidemic-grew-out-of-control/2016/10/22/aea2bf8e-7f71-11e6-8d13-d7c704ef9fd9_story.html; Lenny Bernstein & Scott Higham, *Investigation: U.S. Senator Calls for Investigation of DEA Enforcement Slowdown Amid Opioid Crisis*, Wash. Post, Mar. 6, 2017, https://www.washingtonpost.com/investigations/us-senator-calls-for-investigation-of-dea-enforcement-slowdown/2017/03/06/5846ee60-028b-11e7-b1e9-a05d3c21f7cf_story.html; Eric Eyre, *DEA Agent: "We Had No Leadership" in WV Amid Flood of Pain Pills*, Charleston Gazette-Mail (Feb. 18, 2017), <http://www.wvgazettemail.com/news/20170218/dea-agent-we-had-no-leadership-in-wv-amid-flood-of-pain-pills->.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

1302. The RICO Supply Chain Defendants knowingly and intentionally furnished false or fraudulent information in their reports to the DEA about suspicious orders, and/or omitted material information from reports, records and other document required to be filed with the DEA including the RICO Supply Chain Manufacturer Defendants' applications for production quotas. Specifically, the RICO Supply Chain Defendants were aware of suspicious orders of prescription opioids and the diversion of their prescription opioids into the illicit market and failed to report this information to the DEA in their mandatory reports and their applications for production quotas.

1303. The RICO Supply Chain Defendants used, directed the use of, and/or caused to be used, thousands of interstate mail and wire communications in service of their scheme through virtually uniform misrepresentations, concealments and material omissions regarding their compliance with their mandatory reporting requirements and the actions necessary to carry out their unlawful goal of selling prescription opioids without reporting suspicious orders or the diversion of opioids into the illicit market.

1304. In devising and executing the illegal scheme, the RICO Supply Chain Defendants devised and knowingly carried out a material scheme and/or artifice to defraud by means of materially false or fraudulent pretenses, representations, promises, or omissions of material facts.

1305. For the purpose of executing the illegal scheme, the RICO Supply Chain Defendants committed racketeering acts, which number in the thousands, intentionally and knowingly with the specific intent to advance the illegal scheme. These racketeering acts, which included repeated acts of mail fraud and wire fraud, constituted a pattern of racketeering.

1306. Regardless of any licenses or registrations held by the RICO Supply Chain Defendants to distribute dangerous and harmful drugs, their conduct was not "lawful." The RICO

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

Supply Chain Defendants engaged in a fraudulent and unlawful course of conduct constituting a pattern of racketeering activity.

1307. The pattern of racketeering activity alleged herein and each RICO Supply Chain Defendant's Supply Chain Enterprise are separate and distinct from each other. Likewise, each RICO Supply Chain Defendant is distinct from the Supply Chain Enterprise.

1308. The pattern of racketeering activity alleged herein is continuing as of the date of this Complaint and, upon information and belief, will continue into the future unless enjoined by this Court.

1309. The RICO Supply Chain Defendants' use of the mail and wires includes, but is not limited to, the transmission, delivery, or shipment of the following by the Manufacturer Defendants, the Distributor Defendants, or third parties that were foreseeably caused to be sent as a result of the RICO Supply Chain Defendants' illegal scheme, including but not limited to:

1310. The prescription opioids themselves;

1311. Documents and communications that supported and/or facilitated the RICO Supply Chain Defendants' request for higher aggregate production quotas, individual production quotas, and procurement quotas;

1312. Documents and communications that facilitated the manufacture, purchase and sale of prescription opioids;

1313. RICO Supply Chain Defendants' DEA registrations;

1314. Documents and communications that supported and/or facilitated RICO Supply Chain Defendants' DEA registrations;

1315. RICO Supply Chain Defendants' records and reports that were required to be submitted to the DEA pursuant to 21 U.S.C. § 827;

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

1316. Documents and communications related to the RICO Supply Chain Defendants' mandatory DEA reports pursuant to 21 U.S.C. § 823 and 21 C.F.R. § 1301.74;

1317. Documents intended to facilitate the manufacture and distribution of the RICO Supply Chain Defendants' prescription opioids, including bills of lading, invoices, shipping records, reports and correspondence;

1318. Documents for processing and receiving payment for prescription opioids;

1319. Payments from the Distributors to the Manufacturer Defendants;

1320. Rebates and chargebacks from the Manufacturer Defendants to the Distributors Defendants;

1321. Payments to the RICO Supply Chain Defendants' lobbyists through the PCF;

1322. Payments to the RICO Supply Chain Defendants' trade organizations, like the HDA, for memberships and/or sponsorships;

1323. Deposits of proceeds from the RICO Supply Chain Defendants' manufacture and distribution of prescription opioids; and

1324. Other documents and things, including electronic communications.

1325. The RICO Supply Chain Defendants (and/or their agents), for the purpose of executing the illegal scheme, sent and/or received (or caused to be sent and/or received) by mail or by private or interstate carrier, shipments of prescription opioids and related documents by mail or by private carrier affecting interstate commerce, including the following:

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

Defendant Group Name	Company Names	Drugs		
		Drug Name	Chemical Name	CSA Schedule
Purdue	(1) Purdue Pharma, LP, (2) Purdue Pharma, Inc., (3) The Purdue Frederick Company	OxyContin	Oxycodone hydrochloride extended release	Schedule II
		MS Contin	Morphine sulfate extended release	Schedule II
		Dilaudid	Hydromorphone hydrochloride	Schedule II
		Dilaudid-HP	Hydromorphone hydrochloride	Schedule II
		Butrans	Buprenorphine	Schedule II
		Hysinga ER	Hydrocodone bitrate	Schedule II
		Targiniq ER	Oxycodone hydrochloride	Schedule II
Cephalon	(1) Cephalon, Inc., (2) Teva Pharmaceutical Industries, Ltd., (3) Teva Pharmaceuticals USA, Inc.	Actiq	Fentanyl citrate	Schedule II
		Fentora	Fentanyl citrate	Schedule II
		Generic oxycodone	Oxycodone hydrochloride	Schedule II
Endo	(1) Endo Health Solutions, Inc., (2) Endo Pharmaceuticals Inc., (3) Qualitest Pharmaceuticals, Inc. <i>(wholly-owned subsidiary of Endo)</i>	Opana ER	Oxymorphone hydrochloride extended release	Schedule II
		Opana	Oxymorphone hydrochloride	Schedule II
		Percodan	Oxymorphone hydrochloride and aspirin	Schedule II
		Percocet	Oxymorphone hydrochloride and acetaminophen	Schedule II
		Generic oxycodone		Schedule II
		Generic oxymorphone		Schedule II
		Generic hydromorphone		Schedule II
		Generic hydrocodone		Schedule II
Mallinckrodt	(1) Mallinckrodt plc,	Exalgo	Hydromorphone hydrochloride	Schedule II

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

Defendant Group Name	Company Names	Drugs		
		Drug Name	Chemical Name	CSA Schedule
	(2) Mallinckrodt LLC <i>(wholly-owned subsidiary of Mallinckrodt plc)</i>	Roxicodone	Oxycodone hydrochloride	Schedule II

1326. Each of the RICO Supply Chain Defendants identified shipped, paid for and received payment for the drugs identified above, throughout the United States.

1327. The RICO Supply Chain Defendants used the internet and other electronic facilities to carry out their scheme and conceal the ongoing fraudulent activities. Specifically, the RICO Supply Chain Defendants made misrepresentations about their compliance with Federal and State laws requiring them to identify, investigate and report suspicious orders of prescription opioids and/or diversion of the same into the illicit market.

1328. At the same time, the RICO Supply Chain Defendants misrepresented the superior safety features of their order monitoring programs, ability to detect suspicious orders, commitment to preventing diversion of prescription opioids, and their compliance with all state and federal regulations regarding the identification and reporting of suspicious orders of prescription opioids.

1329. The RICO Supply Chain Defendants utilized the internet and other electronic resources to exchange communications, to exchange information regarding prescription opioid sales, and to transmit payments and rebates/chargebacks.

1330. The RICO Supply Chain Defendants also communicated by U.S. Mail, by interstate facsimile, and by interstate electronic mail with each other and with various other affiliates, regional offices, regulators, distributors, and other third-party entities in furtherance of the scheme.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

1331. The mail and wire transmissions described herein were made in furtherance of the RICO Supply Chain Defendants' scheme and common course of conduct to deceive regulators, the public and the Plaintiffs that these Defendants were complying with their state and federal obligations to identify and report suspicious orders of prescription opioids all while Defendants were knowingly allowing millions of doses of prescription opioids to divert into the illicit drug market. The RICO Supply Chain Defendants' scheme and common course of conduct was to increase or maintain high production quotas for their prescription opioids from which they could profit.

1332. Many of the precise dates of the fraudulent uses of the U.S. mail and interstate wire facilities have been deliberately hidden by Defendants and cannot be alleged without access to Defendants' books and records. However, Plaintiffs have described the types of, and in some instances, occasions on which the predicate acts of mail and/or wire fraud occurred. They include thousands of communications to perpetuate and maintain the scheme, including the things and documents described in the preceding paragraphs.

1333. The RICO Supply Chain Defendants did not undertake the practices described herein in isolation, but as part of a common scheme. Various other persons, firms, and corporations, including third-party entities and individuals not named as defendants in this Complaint, may have contributed to and/or participated in the scheme with these Defendants in these offenses and have performed acts in furtherance of the scheme to increase revenues, increase market share, and /or minimize the losses for the RICO Supply Chain Defendants.

1334. The predicate acts constituted a variety of unlawful activities, each conducted with the common purpose of obtaining significant monies and revenues from the sale of their highly

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

addictive and dangerous drugs. The predicate acts also had the same or similar results, participants, victims, and methods of commission. The predicate acts were related and not isolated events.

1335. The predicate acts all had the purpose of creating the opioid epidemic that substantially injured Plaintiffs' business and property, while simultaneously generating billion-dollar revenue and profits for the RICO Supply Chain Defendants. The predicate acts were committed or caused to be committed by the Defendants through their participation in the Opioid Supply Chain Enterprise and in furtherance of its fraudulent scheme.

1336. As described above, the RICO Supply Chain Defendants were repeatedly warned, fined, and found to be in violation of applicable law and regulations, and yet they persisted. The sheer volume of enforcement actions against the RICO Supply Chain Defendants supports this conclusion that the RICO Supply Chain Defendants operated through a pattern and practice of willfully and intentionally omitting information from their mandatory reports to the DEA as required by 21 C.F.R. § 1301.74.⁶⁰³

1337. Each instance of racketeering activity alleged herein was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, Plaintiffs' Community and the Plaintiff. The RICO Supply Chain Defendants calculated and intentionally crafted the diversion scheme to increase and maintain profits from unlawful sales of opioids, without regard to the effect such behavior would have on this jurisdiction, its citizens or the Plaintiff. The RICO Supply Chain Defendants were aware that Plaintiffs and the citizens of this jurisdiction rely on these Defendants to maintain a closed system of manufacturing and distribution to protect against the non-medical diversion and use of their dangerously addictive opioid drugs.

⁶⁰³ Evaluation and Inspections Div., Office of the Inspector Gen., U.S. Dep't of Justice, *The Drug Enforcement Administration's Adjudication of Registrant Actions* 6 (2014), <https://oig.justice.gov/reports/2014/e1403.pdf>.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

1338. By intentionally refusing to report and halt suspicious orders of their prescription opioids, the RICO Supply Chain Defendants engaged in a fraudulent scheme and unlawful course of conduct constituting a pattern of racketeering activity.

1339. Faced with the reality that they will now be held accountable for the consequences of the opioid epidemic they created, members of the industry resort to “a categorical denial of any criminal behavior or intent.”⁶⁰⁴ Defendants’ actions went far beyond what could be considered ordinary business conduct. For more than a decade, certain Defendants, the “RICO Supply Chain Defendants” (Purdue, Cephalon, Endo, Mallinckrodt, Actavis, McKesson, Cardinal, and AmerisourceBergen) worked together in an illicit enterprise, engaging in conduct that was not only illegal, but in certain respects anti-competitive, with the common purpose and achievement of vastly increasing their respective profits and revenues by exponentially expanding a market that the law intended to restrict.

1340. Knowing that dangerous drugs have a limited place in our society, and that their dissemination and use must be vigilantly monitored and policed to prevent the harm that drug abuse and addiction causes to individuals, society and governments, Congress enacted the Controlled Substances Act (“CSA”). Specifically, through the CSA, which created a closed system of distribution for controlled substances, Congress established an enterprise for good. CSA imposes a reporting duty that cuts across company lines. Regulations adopted under the CSA require that companies who are entrusted with permission to operate within this system cannot simply operate as competitive in an “anything goes” profit-maximizing market. Instead, the statute tasks them to watch over each other with a careful eye for suspicious activity. Driven by greed,

⁶⁰⁴ McKesson Responds to Recent 60 Minutes Story About January 2017 Settlement With the Federal Government, McKesson, <http://www.mckesson.com/about-mckesson/fighting-opioid-abuse/60-minutes-response> (last visited Apr. 21, 2018).

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

Defendants betrayed that trust and subverted the constraints of the CSA's closed system to conduct their own enterprise for evil.

1341. As "registrants" under the CSA, the RICO Supply Chain Defendants are duty bound to identify and report "orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency."⁶⁰⁵

1342. If morality and the law did not suffice, competition dictates that the RICO Supply Chain Defendants would turn in their rivals when they had reason to suspect suspicious activity. Indeed, if a manufacturer or distributor could gain market share by reporting a competitor's illegal behavior (causing it to lose a license to operate, or otherwise inhibit its activity), ordinary business conduct dictates that it would do so. Unfortunately, however, that is not what happened. Instead, knowing that investigations into potential diversion would only lead to shrinking markets, the Rico Supply Chain Defendants elected to operate in a conspiracy of silence, in violation of both the CSA and RICO.

1343. The RICO Supply Chain Defendants' scheme required the participation of all. If any one member broke rank, its compliance activities would highlight deficiencies of the others, and the artificially high quotas they maintained through their scheme would crumble. But, if all the members of the enterprise conducted themselves in the same manner, it would be difficult for the DEA to go after any one of them. Accordingly, through the connections they made as a result of their participation in the Healthcare Distribution Alliance ("HDA"), the RICO Supply Chain Defendants chose to flout the closed system designed to protect the citizens. Publicly, in 2008, they announced their formulation of "Industry Compliance Guidelines: Reporting Suspicious Orders and Prevention Diversion of Controlled Substances." But, privately, the RICO Supply

⁶⁰⁵ 21 C.F.R. § 1301.74(b).

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

Chain Defendants refused to act and through their lobbying efforts, they collectively sought to undermine the impact of the CSA. Indeed, despite the issuance of these Industry Compliance Guidelines, which recognize these Defendants' duties under the law, as illustrated by the subsequent industry-wide enforcement actions and consent orders issued after that time, none of them complied. John Gray, President and CEO of the HDA said to Congress in 2014, it is "difficult to find the right balance between proactive anti-diversion efforts while not inadvertently limiting access to appropriately prescribed and dispensed medications." Yet, the RICO Supply Chain Defendants apparently all found the same profit-maximizing balance—intentionally remaining silent to ensure the largest possible financial return.

1344. As described above, at all relevant times, the RICO Supply Chain Defendants operated as an association-in-fact enterprise formed for the purpose of unlawfully increasing sales, revenues and profits by fraudulently increasing the quotas set by the DEA that would allow them to collectively benefit from a greater pool of prescription opioids to manufacture and distribute. In support of this common purpose and fraudulent scheme, the RICO Supply Chain Defendants jointly agreed to disregard their statutory duties to identify, investigate, halt and report suspicious orders of opioids and diversion of their drugs into the illicit market so that those orders would not result in a decrease, or prevent an increase in, the necessary quotas.

1345. At all relevant times, as described above, the RICO Supply Chain Defendants exerted control over, conducted and/or participated in the Opioid Supply Chain Enterprise by fraudulently claiming that they were complying with their duties under the CSA to identify, investigate and report suspicious orders of opioids in order to prevent diversion of those highly addictive substances into the illicit market, and to halt such unlawful sales, so as to increase production quotas and generate unlawful profits, as follows:

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

1346. The RICO Supply Chain Defendants disseminated false and misleading statements to state and federal regulators claiming that:

- a. the quotas for prescription opioids should be increased;
- b. they were complying with their obligations to maintain effective controls against diversion of their prescription opioids;
- c. they were complying with their obligations to design and operate a system to disclose to the registrant suspicious orders of their prescription opioids;
- d. they were complying with their obligation to notify the DEA of any suspicious orders or diversion of their prescription opioids; and
- e. they did not have the capability to identify suspicious orders of controlled substances.

1347. The Defendants applied political and other pressure on the DOJ and DEA to halt prosecutions for failure to report suspicious orders of prescription opioids and lobbied Congress to strip the DEA of its ability to immediately suspend registrations pending investigation by passing the “Ensuring Patient Access and Effective Drug Enforcement Act.”⁶⁰⁶

1348. The CSA and the Code of Federal Regulations, require the RICO Supply Chain Defendants to make reports to the DEA of any suspicious orders identified through the design and operation of their system to disclose suspicious orders. The failure to make reports as required by the CSA and Code of Federal Regulations amounts to a criminal violation of the statute.

1349. The RICO Supply Chain Defendants knowingly and intentionally furnished false or fraudulent information in their reports to the DEA about suspicious orders, and/or omitted

⁶⁰⁶ *HDMA is Now the Healthcare Distribution Alliance*, Pharmaceutical Commerce, <http://pharmaceuticalcommerce.com/business-and-finance/hdma-now-healthcare-distribution-alliance/> (last updated July 6, 2016); Lenny Bernstein & Scott Higham, *Investigation: The DEA Slowed Enforcement While the Opioid Epidemic Grew Out of Control*, Wash. Post (Oct. 22, 2016), https://www.washingtonpost.com/investigations/the-dea-slowed-enforcement-while-the-opioid-epidemic-grew-out-of-control/2016/10/22/aea2bf8e-7f71-11e6-8d13-d7c704ef9fd9_story.html; Lenny Bernstein & Scott Higham, *Investigation: U.S. Senator Calls for Investigation of DEA Enforcement Slowdown Amid Opioid Crisis*, Wash. Post (Mar. 6, 2017), https://www.washingtonpost.com/investigations/us-senator-calls-for-investigation-of-dea-enforcement-slowdown/2017/03/06/5846ee60-028b-11e7-b1e9-a05d3c21f7cf_story.html; Eric Eyre, *DEA Agent: “We Had no Leadership” in WV Amid Flood of Pain Pills*, Charleston Gazette-Mail (Feb. 18, 2017), <http://www.wvgazettemail.com/news/20170218/dea-agent-we-had-no-leadership-in-wv-amid-flood-of-pain-pills->.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

material information from reports, records and other document required to be filed with the DEA including the Marketing Defendants' applications for production quotas. Specifically, the RICO Supply Chain Defendants were aware of suspicious orders of prescription opioids and the diversion of their prescription opioids into the illicit market, and failed to report this information to the DEA in their mandatory reports and their applications for production quotas.

1350. The RICO Supply Chain Defendants used, directed the use of, and/or caused to be used, thousands of interstate mail and wire communications in service of their scheme through virtually uniform misrepresentations, concealments and material omissions regarding their compliance with their mandatory reporting requirements and the actions necessary to carry out their unlawful goal of selling prescription opioids without reporting suspicious orders or the diversion of opioids into the illicit market.

1351. In devising and executing the illegal scheme, the RICO Supply Chain Defendants devised and knowingly carried out a material scheme and/or artifice to defraud by means of materially false or fraudulent pretenses, representations, promises, or omissions of material facts.

1352. For the purpose of executing the illegal scheme, the RICO Supply Chain Defendants committed racketeering acts, which number in the thousands, intentionally and knowingly with the specific intent to advance the illegal scheme. These racketeering acts, which included repeated acts of mail fraud and wire fraud, constituted a pattern of racketeering.

1353. The RICO Supply Chain Defendants' use of the mail and wires includes, but is not limited to, the transmission, delivery, or shipment of the following by the Marketing Defendants, the Distributor Defendants, or third parties that were foreseeably caused to be sent as a result of the RICO Supply Chain Defendants' illegal scheme, including but not limited to:

- a. The prescription opioids themselves;

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

- b. Documents and communications that supported and/or facilitated the RICO Supply Chain Defendants' request for higher aggregate production quotas, individual production quotas, and procurement quotas;
- c. Documents and communications that facilitated the manufacture, purchase and sale of prescription opioids;
- d. RICO Supply Chain Defendants' DEA registrations;
- e. Documents and communications that supported and/or facilitated RICO Supply Chain Defendants' DEA registrations;
- f. RICO Supply Chain Defendants' records and reports that were required to be submitted to the DEA pursuant to 21 U.S.C. § 827;
- g. Documents and communications related to the RICO Supply Chain Defendants' mandatory DEA reports pursuant to 21 U.S.C. § 823 and 21 C.F.R. § 1301.74;
- h. Documents intended to facilitate the manufacture and distribution of the RICO Supply Chain Defendants' prescription opioids, including bills of lading, invoices, shipping records, reports and correspondence;
- i. Documents for processing and receiving payment for prescription opioids;
- j. Payments from the Distributors to the Marketing Defendants;
- k. Rebates and chargebacks from the Marketing Defendants to the Distributor Defendants;
- l. Payments to the RICO Supply Chain Defendants' lobbyists through the PCF;
- m. Payments to the RICO Supply Chain Defendants' trade organizations, like the HDA, for memberships and/or sponsorships;
- n. Deposits of proceeds from the RICO Supply Chain Defendants' manufacture and distribution of prescription opioids; and
- o. Other documents and things, including electronic communications.

1354. The RICO Supply Chain Defendants (and/or their agents), for the purpose of executing the illegal scheme, sent and/or received (or caused to be sent and/or received) by mail or by private or interstate carrier, shipments of prescription opioids and related documents by mail or by private carrier affecting interstate commerce, including the following:

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

Defendant Group Name	Company Names	Drugs		
		Drug Name	Chemical Name	CSA Schedule
Purdue	(1) Purdue Pharma, LP, (2) Purdue Pharma, Inc., (3) The Purdue Frederick Company	OxyContin	Oxycodone hydrochloride extended release	Schedule II
		MS Contin	Morphine sulfate extended release	Schedule II
		Dilaudid	Hydromorphone hydrochloride	Schedule II
		Dilaudid-HP	Hydromorphone hydrochloride	Schedule II
		Butrans	Buprenorphine	Schedule II
		Hysinga ER	Hydrocodone bitrate	Schedule II
Cephalon	(1) Cephalon, Inc., (2) Teva Pharmaceutical Industries, Ltd., (3) Teva Pharmaceuticals USA, Inc.	Actiq	Fentanyl citrate	Schedule II
		Fentora	Fentanyl citrate	Schedule II
		Generic oxycodone	Oxycodone hydrochloride	Schedule II
Endo	(1) Endo Health Solutions, Inc., (2) Endo Pharmaceuticals Inc., (3) Qualitest Pharmaceuticals, Inc. <i>(wholly-owned subsidiary of Endo)</i>	Opana ER	Oxymorphone hydrochloride extended release	Schedule II
		Opana	Oxymorphone hydrochloride	Schedule II
		Percodan	Oxymorphone hydrochloride and aspirin	Schedule II
		Percocet	Oxymorphone hydrochloride and acetaminophen	Schedule II
		Generic oxycodone		Schedule II
		Generic oxymorphone		Schedule II
		Generic hydromorphone		Schedule II
		Generic hydrocodone		Schedule II
Mallinckrodt	(1) Mallinckrodt plc,	Exalgo	Hydromorphone hydrochloride	Schedule II

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

Defendant Group Name	Company Names (2) Mallinckrodt LLC (wholly-owned subsidiary of Mallinckrodt plc)	Drugs		
		Drug Name	Chemical Name	CSA Schedule
		Roxicodone	Oxycodone hydrochloride	Schedule II

1355. Each of the RICO Supply Chain Defendants identified manufactured, paid

for and received payment for the drugs identified above, throughout the United States.

1356. The RICO Supply Chain Defendants used the internet and other electronic facilities to carry out their scheme and conceal the ongoing fraudulent activities. Specifically, the RICO Supply Chain Defendants made misrepresentations about their compliance with Federal and State laws requiring them to identify, investigate and report suspicious orders of prescription opioids and/or diversion of the same into the illicit market.

1357. At the same time, the RICO Supply Chain Defendants misrepresented the superior safety features of their order monitoring programs, ability to detect suspicious orders, commitment to preventing diversion of prescription opioids, and their compliance with all state and federal regulations regarding the identification and reporting of suspicious orders of prescription opioids.

1358. The RICO Supply Chain Defendants utilized the internet and other electronic resources to exchange communications, to exchange information regarding prescription opioid sales, and to transmit payments and rebates/chargebacks.

1359. The RICO Supply Chain Defendants also communicated by U.S. Mail, by interstate facsimile, and by interstate electronic mail with each other and with various other affiliates, regional offices, regulators, distributors, and other third-party entities in furtherance of the scheme.

1360. The mail and wire transmissions described herein were made in furtherance of the RICO Supply Chain Defendants' scheme and common course of conduct to deceive regulators, the public and the Plaintiff that these Defendants were complying with their state and federal

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

obligations to identify and report suspicious orders of prescription opioids all while Defendants were knowingly allowing millions of doses of prescription opioids to divert into the illicit drug market. The RICO Supply Chain Defendants' scheme and common course of conduct was to increase or maintain high production quotas for their prescription opioids from which they could profit.

1361. Many of the precise dates of the fraudulent uses of the U.S. mail and interstate wire facilities have been deliberately hidden by Defendants and cannot be alleged without access to Defendants' books and records. However, Plaintiff has described the types of, and in some instances, occasions on which the predicate acts of mail and/or wire fraud occurred. They include thousands of communications to perpetuate and maintain the scheme, including the things and documents described in the preceding paragraphs.

1362. The RICO Supply Chain Defendants did not undertake the practices described herein in isolation, but as part of a common scheme. Various other persons, firms, and corporations, including third-party entities and individuals not named as defendants in this Complaint, may have contributed to and/or participated in the scheme with these Defendants in these offenses and have performed acts in furtherance of the scheme to increase revenues, increase market share, and /or minimize the losses for the RICO Supply Chain Defendants.

1363. The predicate acts constituted a variety of unlawful activities, each conducted with the common purpose of obtaining significant monies and revenues from the sale of their highly addictive and dangerous drugs. The predicate acts also had the same or similar results, participants, victims, and methods of commission. The predicate acts were related and not isolated events.

1364. The predicate acts all had the purpose of creating the opioid epidemic that substantially injured Plaintiff's business and property, while simultaneously generating billion-

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

dollar revenue and profits for the RICO Supply Chain Defendants. The predicate acts were committed or caused to be committed by the Defendants through their participation in the Opioid Supply Chain Enterprise and in furtherance of its fraudulent scheme.

1365. As described above, the RICO Supply Chain Defendants were repeatedly warned, fined, and found to be in violation of applicable law and regulations, and yet they persisted. The sheer volume of enforcement actions against the RICO Supply Chain Defendants supports this conclusion that the RICO Supply Chain Defendants operated through a pattern and practice of willfully and intentionally omitting information from their mandatory reports to the DEA as required by 21 C.F.R. § 1301.74.

1366. Each instance of racketeering activity alleged herein was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, Plaintiff's communities and the Plaintiff. The RICO Supply Chain Defendants calculated and intentionally crafted the diversion scheme to increase and maintain profits from unlawful sales of opioids, without regard to the effect such behavior would have on this jurisdiction, its citizens or the Plaintiff. The RICO Supply Chain Defendants were aware that Plaintiff and the citizens of this jurisdiction rely on these Defendants to maintain a closed system of manufacturing and distribution to protect against the non-medical diversion and use of their dangerously addictive opioid drugs.

1367. By intentionally refusing to report and halt suspicious orders of their prescription opioids, the RICO Supply Chain Defendants engaged in a fraudulent scheme and unlawful course of conduct constituting a pattern of racketeering activity.

C. Facts Pertaining to Punitive Damages

1368. As set forth above, Defendants acted deliberately to increase sales of, and profits from, opioid drugs. The Marketing Defendants knew there was no support for their claims that

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

addiction was rare, that addiction risk could be effectively managed, that signs of addiction were merely “pseudoaddiction,” that withdrawal is easily managed, that higher doses pose no significant additional risks, that long-term use of opioids improves function, or that time-release or abuse-deterrent formulations would prevent addiction or abuse. Nonetheless, they knowingly promoted these falsehoods in order to increase the market for their addictive drugs.

1369. All of the Defendants, moreover, knew that large and suspicious quantities of opioids were being poured into communities throughout the United States, yet, despite this knowledge, took no steps to report suspicious orders, control the supply of opioids, or otherwise prevent diversion. Indeed as described above, Defendants acted in concert together to maintain high levels of quotas for their products and to ensure that suspicious orders would not be reported to regulators.

1370. Defendants’ conduct was so willful and deliberate that it continued in the face of numerous enforcement actions, fines, and other warnings from state and local governments and regulatory agencies. Defendants paid their fines, made promises to do better, and continued on with their marketing and supply schemes. This ongoing course of conduct knowingly, deliberately and repeatedly threatened and accomplished harm and risk of harm to public health and safety, and large scale economic loss to communities and government liabilities across the country.

1371. Defendants’ actions demonstrated both malice and also aggravated and egregious fraud. Defendants engaged in the conduct alleged herein with a conscious disregard for the rights and safety of other persons, even though that conduct had a great probability of causing substantial harm. Marketing Defendants’ fraudulent wrongdoing was also particularly gross.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

1. The Marketing Defendants Persisted in Their Fraudulent Scheme Despite Repeated Admonitions, Warnings, and Even Prosecutions

1372. So determined were the Marketing Defendants to sell more opioids that they simply ignored multiple admonitions, warnings and prosecutions. These governmental and regulatory actions included:

a. FDA Warnings to Janssen Failed to Deter Janssen’s Misleading Promotion of Duragesic

1373. On February 15, 2000, the FDA sent Janssen a letter concerning the dissemination of “homemade” promotional pieces that promoted the Janssen drug Duragesic in violation of the Federal Food, Drug, and Cosmetic Act. In a subsequent letter, dated March 30, 2000, the FDA explained that the “homemade” promotional pieces were “false or misleading because they contain misrepresentations of safety information, broaden Duragesic’s indication, contain unsubstantiated claims, and lack fair balance.” The March 30, 2000 detailed numerous ways in which Janssen’s marketing was misleading.

1374. The letter did not stop Janssen. On September 2, 2004, the U.S. Department of Health and Human Services (“HHS”) sent Janssen a warning letter concerning Duragesic due to “false or misleading claims about the abuse potential and other risks of the drug, and . . . unsubstantiated effectiveness claims for Duragesic,” including, specifically, “suggesting that Duragesic has a lower potential for abuse compared to other opioid products.” The September 2, 2004 letter detailed a series of unsubstantiated, false or misleading claims.

1375. One year later, Janssen was still at it. On July 15, 2005, the FDA issued a public health advisory warning doctors of deaths resulting from the use of Duragesic and its generic competitor, manufactured by Mylan N.V. The advisory noted that the FDA had been “examining the circumstances of product use to determine if the reported adverse events may be related to inappropriate use of the patch” and noted the possibility “that patients and physicians might be

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

unaware of the risks” of using the fentanyl transdermal patch, which is a potent opioid analgesic approved only for chronic pain in opioid-tolerant patients that could not be treated by other drugs.

a. **Governmental Action, Including Large Monetary Fines, Failed to Stop Cephalon from Falsely Marketing Actiq for Off-Label Uses**

1376. On September 29, 2008, Cephalon finalized and entered into a corporate integrity agreement with the Office of the Inspector General of HHS and agreed to pay \$425 million in civil and criminal penalties for its off-label marketing of Actiq and two other drugs (Gabitril and Provigil). According to a DOJ press release, Cephalon had trained sales representatives to disregard restrictions of the FDA-approved label, employed sales representatives and healthcare professionals to speak to physicians about off-label uses of the three drugs and funded CME to promote off-label uses.

1377. Notwithstanding letters, an FDA safety alert, DOJ and state investigations, and the massive settlement, Cephalon has continued its deceptive marketing strategy.

b. **FDA Warnings Did Not Prevent Cephalon from Continuing False and Off-Label Marketing of Fentora**

1378. On September 27, 2007, the FDA issued a public health advisory to address numerous reports that patients who did not have cancer or were not opioid tolerant had been prescribed Fentora, and death or life-threatening side effects had resulted. The FDA warned: “Fentora should not be used to treat any type of short-term pain.” Indeed, FDA specifically denied Cephalon’s application, in 2008, to broaden the indication of Fentora to include treatment of non-cancer breakthrough pain and use in patients who were not already opioid-tolerant.

1379. Flagrantly disregarding the FDA’s refusal to broaden the indication for Fentora, Cephalon nonetheless marketed Fentora beyond its approved indications. On March 26, 2009, the FDA warned Cephalon against its misleading advertising of Fentora (“Warning Letter”). The Warning Letter described a Fentora Internet advertisement as misleading because it purported to

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

broaden “the indication for Fentora by implying that any patient with cancer who requires treatment for breakthrough pain is a candidate for Fentora . . . when this is not the case.” It further criticized Cephalon’s other direct Fentora advertisements because they did not disclose the risks associated with the drug.

1380. Despite this warning, Cephalon continued to use the same sales tactics to push Fentora as it did with Actiq. For example, on January 13, 2012, Cephalon published an insert in Pharmacy Times titled “An Integrated Risk Evaluation and Mitigation Strategy (REMS) for FENTORA (Fentanyl Buccal Tablet) and ACTIQ (Oral Transmucosal Fentanyl Citrate).” Despite the repeated warnings of the dangers associated with the use of the drugs beyond their limited indication, as detailed above, the first sentence of the insert states: “It is well recognized that the judicious use of opioids can facilitate effective and safe management of chronic pain.”

c. **A Guilty Plea and a Large Fine Did Not Deter Purdue from Continuing Its Fraudulent Marketing of OxyContin**

1381. In May 2007, Purdue and three of its executives pled guilty to federal charges of misbranding OxyContin in what the company acknowledged was an attempt to mislead doctors about the risk of addiction. Purdue was ordered to pay \$600 million in fines and fees. In its plea, Purdue admitted that its promotion of OxyContin was misleading and inaccurate, misrepresented the risk of addiction and was unsupported by science. Additionally, Michael Friedman the company’s president, pled guilty to a misbranding charge and agreed to pay \$19 million in fines; Howard R. Udell, Purdue’s top lawyer, also pled guilty and agreed to pay \$8 million in fines; and Paul D. Goldenheim, its former medical director, pled guilty as well and agreed to pay \$7.5 million in fines.

1382. Nevertheless, even after the settlement, Purdue continued to pay doctors on speakers’ bureaus to promote the liberal prescribing of OxyContin for chronic pain and fund

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

seemingly neutral organizations to disseminate the message that opioids were non-addictive as well as other misrepresentations. At least until early 2018, Purdue continued to deceptively market the benefits of opioids for chronic pain while diminishing the associated dangers of addiction. After Purdue made its guilty plea in 2007, it assembled an army of lobbyists to fight any legislative actions that might encroach on its business. Between 2006 and 2015, Purdue and other painkiller producers, along with their associated nonprofits, spent nearly \$900 million dollars on lobbying and political contributions—eight times what the gun lobby spent during that period.

2. Repeated Admonishments and Fines Did Not Stop Defendants from Ignoring Their Obligations to Control the Supply Chain and Prevent Diversion

1383. Defendants were repeatedly admonished and even fined by regulatory authorities, but continued to disregard their obligations to control the supply chain of dangerous opioids and to institute controls to prevent diversion.

1384. In a *60 Minutes* interview last fall, former DEA agent Joe Rannazzisi described Defendants' industry as "out of control," stating that "[w]hat they wanna do, is do what they wanna do, and not worry about what the law is. And if they don't follow the law in drug supply, people die. That's just it. People die." He further explained that:

JOE RANNAZZISI: The three largest distributors are Cardinal Health, McKesson, and AmerisourceBergen. They control probably 85 or 90 percent of the drugs going downstream.

[INTERVIEWER]: You know the implication of what you're saying, that these big companies knew that they were pumping drugs into American communities that were killing people.

JOE RANNAZZISI: That's not an implication, that's a fact. That's exactly what they did.

1385. Another DEA veteran similarly stated that these companies failed to make even a "good faith effort" to "do the right thing." He further explained that "I can tell you with 100

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

percent accuracy that we were in there on multiple occasions trying to get them to change their behavior. And they just flat out ignored us."

1386. Government actions against the Defendants with respect to their obligations to control the supply chain and prevent diversion include:

- f. On April 24, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the AmerisourceBergen Orlando, Florida distribution center ("Orlando Facility") alleging failure to maintain effective controls against diversion of controlled substances. On June 22, 2007, AmerisourceBergen entered into a settlement that resulted in the suspension of its DEA registration;
- g. On November 28, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Auburn, Washington Distribution Center ("Auburn Facility") for failure to maintain effective controls against diversion of hydrocodone;
- h. On December 5, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Lakeland, Florida Distribution Center ("Lakeland Facility") for failure to maintain effective controls against diversion of hydrocodone;
- i. On December 7, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Swedesboro, New Jersey Distribution Center ("Swedesboro Facility") for failure to maintain effective controls against diversion of hydrocodone;
- j. On January 30, 2008, the DEA issued an Order to Show Cause against the Cardinal Health Stafford, Texas Distribution Center ("Stafford Facility") for failure to maintain effective controls against diversion of hydrocodone;
- k. On September 30, 2008, Cardinal Health entered into a Settlement and Release Agreement and Administrative Memorandum of Agreement with the DEA related to its Auburn, Lakeland, Swedesboro and Stafford Facilities. The document also referenced allegations by the DEA that Cardinal failed to maintain effective controls against the diversion of controlled substances at its distribution facilities located in McDonough, Georgia ("McDonough Facility"), Valencia, California ("Valencia Facility") and Denver, Colorado ("Denver Facility");
- l. On February 2, 2012, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health's Lakeland Facility for failure to maintain effective controls against diversion of oxycodone; and

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

m. On December 23, 2016, Cardinal Health agreed to pay a \$44 million fine to the DEA to resolve the civil penalty portion of the administrative action taken against its Lakeland Facility; and.

1387. McKesson's conscious and deliberate disregard of its obligations was especially flagrant. On May 2, 2008, McKesson Corporation entered into an Administrative Memorandum of Agreement ("2008 McKesson MOA") with the DEA which provided that McKesson would "maintain a compliance program designed to detect and prevent the diversion of controlled substances, inform DEA of suspicious orders required by 21 C.F.R. § 1301.74(b), and follow the procedures established by its Controlled Substance Monitoring Program."

1388. Despite its 2008 agreement with DEA, McKesson continued to fail to report suspicious orders between 2008 and 2012 and did not fully implement or follow the monitoring program it agreed to. It failed to conduct adequate due diligence of its customers, failed to keep complete and accurate records in the CSMP files maintained for many of its customers and bypassed suspicious order reporting procedures set forth in the CSMP. It failed to take these actions despite its awareness of the great probability that its failure to do so would cause substantial harm.

1389. On January 5, 2017, McKesson Corporation entered into an Administrative Memorandum Agreement with the DEA wherein it agreed to pay a \$150 million civil penalty for violation of the 2008 MOA as well as failure to identify and report suspicious orders at its facilities in Aurora CO, Aurora IL, Delran NJ, LaCrosse WI, Lakeland FL, Landover MD, La Vista NE, Livonia MI, Methuen MA, Sante Fe Springs CA, Washington Courthouse OH and West Sacramento CA. McKesson's 2017 agreement with DEA documents that McKesson continued to breach its admitted duties by "fail[ing] to properly monitor its sales of controlled substances and/or report suspicious orders to DEA, in accordance with McKesson's obligations."

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

1390. As the *Washington Post* and *60 Minutes* recently reported, DEA staff recommended a much larger penalty than the \$150 million ultimately agreed to for McKesson's continued and renewed breach of its duties, as much as a billion dollars, and delicensing of certain facilities. A DEA memo outlining the investigative findings in connection with the administrative case against 12 McKesson distribution centers included in the 2017 Settlement stated that McKesson “[s]upplied controlled substances in support of criminal diversion activities”; “[i]gnored blatant diversion”; had a “[p]attern of raising thresholds arbitrarily”; “[f]ailed to review orders or suspicious activity”; and “[i]gnored [the company’s] own procedures designed to prevent diversion.”

1391. On December 17, 2017, CBS aired an episode of *60 Minutes* featuring Assistant Special Agent Schiller, who described McKesson as a company that killed people for its own financial gain and blatantly ignored the CSA requirement to report suspicious orders:

DAVID SCHILLER: If they would stayed in compliance with their authority and held those that they’re supplying the pills to, the epidemic would be nowhere near where it is right now. Nowhere near.

* * *

They had hundreds of thousands of suspicious orders they should have reported, and they didn’t report any. There’s not a day that goes by in the pharmaceutical world, in the McKesson world, in the distribution world, where there’s not something suspicious. It happens every day.

[INTERVIEWER:] And they had none.

DAVID SCHILLER: They weren’t reporting any. I mean, you have to understand that, nothing was suspicious?⁶⁰⁷

1392. Following the 2017 settlement, McKesson shareholders made a books and records request of the company. According to a separate action pending on their behalf, the Company’s records show that the Company’s Audit Committee failed to monitor McKesson’s information

⁶⁰⁷ Bill Whitaker, *Whistleblowers: DEA Attorneys Went Easy on McKesson, the Country’s Largest Drug Distributor*, CBS News (Dec. 17, 2017), <https://www.cbsnews.com/news/whistleblowers-deaattorneys-went-easy-on-mckesson-the-countrys-largest-drug-distributor/>.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

reporting system to assess the state of the Company's compliance with the CSA and McKesson's 2008 Settlements. More particularly, the shareholder action alleges that the records show that in October 2008, the Audit Committee had an initial discussion of the 2008 Settlements and results of internal auditing, which revealed glaring omissions; specifically:

- a. some customers had "not yet been assigned thresholds in the system to flag large shipments of controlled substances for review";
- b. "[d]ocumentation evidencing new customer due diligence was incomplete";
- c. "documentation supporting the company's decision to change thresholds for existing customers was also incomplete"; and
- d. Internal Audit "identified opportunities to enhance the Standard Operating Procedures."

1393. Yet, instead of correcting these deficiencies, after that time, for a period of more than four years, the Audit Committee failed to address the CSMP or perform any more audits of McKesson's compliance with the CSA or the 2008 Settlements, the shareholder action's description of McKesson's internal documents reveals. During that period of time, McKesson's Audit Committee failed to inquire whether the Company was in compliance with obligations set forth in those agreements and with the controlled substances regulations more generally. It was only in January 2013 that the Audit Committee received an Internal Audit report touching on these issues.

1394. In short, McKesson, was "neither rehabilitated nor deterred by the 2008 [agreement]," as a DEA official working on the case noted. Quite the opposite, "their bad acts continued and escalated to a level of egregiousness not seen before." According to statements of "DEA investigators, agents and supervisors who worked on the McKesson case" reported in the *Washington Post*, "the company paid little or no attention to the unusually large and frequent orders placed by pharmacies, some of them knowingly supplying the drug rings." "Instead, the DEA

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

officials said, the company raised its own self-imposed limits, known as thresholds, on orders from pharmacies and continued to ship increasing amounts of drugs in the face of numerous red flags.”

1395. Since at least 2002, Purdue has maintained a database of health care providers suspected of inappropriately prescribing OxyContin or other opioids. Physicians could be added to this database based on observed indicators of illicit prescribing such as excessive numbers of patients, cash transactions, patient overdoses, and unusual prescribing of the highest-strength pills (80 mg OxyContin pills or “80s,” as they were known on the street, were a prime target for diversion). Purdue claims that health care providers added to the database no longer were detailed, and that sales representatives received no compensation tied to these providers’ prescriptions.

1396. Yet, Purdue failed to cut off these providers’ opioid supply at the pharmacy level—meaning Purdue continued to generate sales revenue from their prescriptions—and failed to report these providers to state medical boards or law enforcement. Purdue’s former senior compliance officer acknowledged in an interview with the *Los Angeles Times* that in five years of investigating suspicious pharmacies, the company never stopped the supply of its opioids to a pharmacy, even where Purdue employees personally witnessed the diversion of its drugs.

1397. The same was true of prescribers. For example, as discussed above, despite Purdue’s knowledge of illicit prescribing from one Los Angeles clinic which its district manager called an “organized drug ring” in 2009, Purdue did not report its suspicions until long after law enforcement shut it down and not until the ring prescribed more than 1.1 million OxyContin tablets.

1398. The New York Attorney General found that Purdue placed 103 New York health care providers on its “No-Call” List between January 1, 2008 and March 7, 2015, and yet that Purdue’s sales representatives had detailed approximately two-thirds of these providers, some

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

quite extensively, making more than a total of 1,800 sales calls to their offices over a six-year period.

1399. The New York Attorney General similarly found that Endo knew, as early as 2011, that Opana ER was being abused in New York, but certain sales representatives who detailed New York health care providers testified that they did not know about any policy or duty to report problematic conduct. The New York Attorney General further determined that Endo detailed health care providers who were subsequently arrested or convicted for illegal prescribing of opioids a total of 326 times, and these prescribers collectively wrote 1,370 prescriptions for Opana ER (although the subsequent criminal charges at issue did not involve Opana ER).

1400. As all of the governmental actions against the Marketing Defendants and against all the Defendants shows, Defendants knew that their actions were unlawful, and yet deliberately refused to change their practices because compliance with their legal obligations would have decreased their sales and their profits.

CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF

**Common Law Public Nuisance
(Against All Defendants)**

1401. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein unless inconsistent with the allegations in this Count, and further alleges:

1402. Defendants created and maintained a public nuisance which proximately caused injury to Plaintiff.

1403. Defendants repeatedly engaged in unlawful and wrongful conduct which unreasonably interfered with and had a substantial impact upon the public health, giving rise to the opioid epidemic.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

1404. A public nuisance results from conduct that caused an unreasonable and substantial interference with a right common to the general public, which is the proximate cause of, and/or substantial factor leading to, Plaintiffs' injury. *See Restatement Second, Torts § 821B.*⁶⁰⁸

1405. Defendants have created and maintained a public nuisance by marketing, distributing, selling opioids, and/or exacerbating the flood of opioids into Plaintiffs' Community in ways that unreasonably interfere with the public health, welfare, and safety in Plaintiffs' Community. Plaintiffs and the residents of Plaintiffs' Community have a common right to be free from such conduct and to be free from conduct that creates a disturbance and reasonable apprehension of danger to person and property.

1406. Plaintiffs have standing to bring claims for public nuisance due to the opioid epidemic affecting and causing harm in Plaintiffs' Community.

1407. West Virginia has adopted a "broad and flexible definition" of a nuisance which is "adaptable to a wide variety of factual situations":

A public nuisance is an act or condition that unlawfully operates to hurt or inconvenience an indefinite number of persons. The distinction between a public nuisance and a private nuisance is that the former affects the general public, and the latter injures one person or a limited number of persons only. Ordinarily, a suit to abate a public nuisance cannot be maintained by an individual in his private capacity, as it is the duty of the proper public officials to vindicate the rights of the public.⁶⁰⁹

⁶⁰⁸ See also *Rhodes v. E.I. du Pont de Nemours and Company*, 657 F.Supp.2d 751, 768 (S.D. W.Va. 2009) (West Virginia's definition of nuisance is "consistent with the Restatement (Second) of Torts § 821B(1)." (quoting *Duff v. Morgantown Energy Assocs. (M.E.A.)*, 187 W.Va. 712, 421 S.E.2d 253, 257 n.6 (1992)).

⁶⁰⁹ *Sharon Steel Corp. v. City of Fairmont*, 334 S.E.2d 616, 620 (W. Va. 1985) (citing Restatement (Second) of Torts § 821B (1979)); see also *State ex rel. Smith v. Kermit Lumber & Pressure Treating Co.*, 488 S.E.2d 901, 921 (W. Va. 1997).

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

1408. A public nuisance is an unreasonable interference with a right common to the general public. Circumstances that may sustain a holding that an interference with a public right is unreasonable include the following:

- d. Whether the conduct involves a significant interference with the public health, the public safety, the public peace, the public comfort or the public convenience, or
- e. whether the conduct is proscribed by a statute, ordinance or administrative regulation, or
- f. whether the conduct is of a continuing nature or has produced a permanent or long-lasting effect, and, as the actor knows or has reason to know, has a significant effect upon the public right.⁶¹⁰

1409. A balancing test to assist in determining the existence of a nuisance is whether the “gravity of the harm outweighs the social value of the activity alleged to cause the harm.”⁶¹¹

1410. Plaintiffs and Plaintiffs’ Community have a common right to be free from conduct that creates an unreasonable jeopardy to the public health, welfare and safety, and to be free from conduct that creates a disturbance and reasonable apprehension of danger to person and property. Defendants injuriously affected public rights, including the right to public health, public safety, public peace, and public comfort of the people of the Plaintiffs’ Community.

1411. The consequences of Defendants’ wrongful and illegal actions as set forth above have also resulted in an intentional invasion of the interest of Plaintiffs and Plaintiffs’ Community in the use and enjoyment of the public and private land comprising Plaintiffs’ corporate boundaries.

⁶¹⁰ RESTATEMENT (SECOND) OF TORTS § 821B (1979); Barker v. Naik, No. 2:17-CV-04387, 2018 WL 3824376, at *3 (S.D.W. Va. Aug. 10, 2018) (noting the consistency with the West Virginia Supreme Court’s definition of public nuisance); see also *Rhodes v. E.I. du Pont de Nemours & Co.*, 657 F. Supp. 2d 751, 768 (S.D.W. Va. 2009) *aff’d in part, appeal dismissed in part*, 636 F.3d 88 (4th Cir. 2011).

⁶¹¹ *Duff v. Morgantown Energy Assocs. (M.E.A.)*, 421 S.E.2d 253, 257 (W. Va. 1992); see also Keith N. Hylton, *The Economics of Public Nuisance Law and the New Enforcement Actions*, 18 SUP. CT. ECON. REV. 43, 44 (2010) (“Nuisance law induces actors to choose socially optimal activity levels by imposing liability when externalized costs are far in excess of externalized benefits or far in excess of background external costs.”).

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

1412. The consequences of Defendants' wrongful and illegal actions as set forth above have further resulted in environmental contamination and/or damage to Plaintiffs' property and property in Plaintiffs' Community.

1413. The public nuisance is a public nuisance because Defendants' nuisance-creating conduct was intentional and unreasonable and/or violated statutes which established specific legal requirements for the protection of others.

1414. Defendants have created and maintained a public nuisance through their ongoing conduct of marketing, distributing and selling opioids, which are dangerously addictive drugs, and/or exacerbating the flood of opioids, in a manner which caused prescriptions and sales of opioids to skyrocket in Plaintiffs' Community, flooded Plaintiffs' Community with opioids, and facilitated and encouraged the flow and diversion of opioids into an illegal, secondary market, resulting in devastating consequences to Plaintiffs and the residents of Plaintiffs' Community.

1415. Defendants know, and have known, that their intentional, unreasonable, and unlawful conduct will cause, and has caused, opioids to be used and possessed illegally and that their conduct has produced an ongoing nuisance that has had, and will continue to have, a detrimental effect upon the public health, welfare, safety, peace, comfort, and convenience of Plaintiffs and Plaintiffs' Community.

1416. The interference is unreasonable because Defendants' nuisance-creating conduct:

- a. Involves a significant interference with the public health, the public safety, the public peace, the public comfort, and/or the public convenience;
- b. At all relevant times was and is proscribed by state and federal laws and regulations; and/or
- c. Is of a continuing nature and, as Defendants know, has had and is continuing to have a significant effect upon rights common to the general public, including the public health, the public safety, the public peace, the public comfort, and/or the public convenience.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

1417. The significant interference with rights common to the general public is described in detail throughout this Complaint and includes:

- a. The creation and fostering of an illegal, secondary market for prescription opioids;
- b. Easy access to prescription opioids by children and teenagers;
- c. A staggering increase in opioid abuse, addiction, overdose, injuries, and deaths;
- d. Infants being born addicted to opioids due to prenatal exposure, causing severe withdrawal symptoms and lasting developmental impacts;
- e. Employers have lost the value of productive and healthy employees; and
- f. Increased costs and expenses for Plaintiffs relating to healthcare services, law enforcement, the criminal justice system, social services, education systems, and property maintenance and clean-up.

1418. Defendants intentionally, unreasonably, and/or unlawfully deceptively marketed and/or pushed as many opioids onto the market as possible, fueling addiction to and diversion of these powerful narcotics, resulting in increased addiction and abuse, an elevated level of crime, death and injuries to the residents of Plaintiffs' Community, a higher level of fear, discomfort and inconvenience to the residents of Plaintiffs' Community, and direct costs to Plaintiffs and Plaintiffs' Community.

1419. Each Defendant is liable for creating the public nuisance because the intentional and unreasonable and/or unlawful conduct of each Defendant was a substantial factor in producing the public nuisance and harm to Plaintiff.

1420. Defendants' conduct constitutes a violation of federal and West Virginia law. In the sale and distribution of opioids in West Virginia and Plaintiffs' Community, Defendants

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

violated federal law, including, but not limited to, 21 U.S.C.A. § 823 and 21 C.F.R. § 1301.74, and West Virginia law, including, but not limited to W. Va. Code § 60A-8-7(c)(1)(I); W. Va. Code § 60A-8-7(c)(3); W. Va. C.S.R. § 15- 2-4. The aforesaid statutes and regulations are public safety statutes and regulations.

1421. Defendants' unlawful nuisance-creating conduct includes violating federal and West Virginia statutes and regulations, including the controlled substances laws, by:

- a. Distributing and selling opioids in ways that facilitated and encouraged their flow into the illegal, secondary market;
- b. Distributing and selling opioids without maintaining effective controls against the diversion of opioids;
- c. Choosing not to effectively monitor for suspicious orders;
- d. Choosing not to investigate suspicious orders;
- e. Choosing not to report suspicious orders;
- f. Choosing not to stop or suspend shipments of suspicious orders;
- g. Distributing and selling opioids prescribed by "pill mills" when Defendants knew or should have known the opioids were being prescribed by "pill mills;" and/or
- h. Exacerbating the flood of opioids into Plaintiffs' Community.

1422. Defendants' intentional and unreasonable nuisance-creating conduct, for which the gravity of the harm outweighs the utility of the conduct, includes:

- a. Distributing and selling opioids in ways that facilitated and encouraged their flow into the illegal, secondary market;

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

- b. Distributing and selling opioids without maintaining effective controls against the diversion of opioids;
- c. Choosing not to effectively monitor for suspicious orders;
- d. Choosing not to investigate suspicious orders;
- e. Choosing not to report suspicious orders;
- f. Choosing not to stop or suspend shipments of suspicious orders; and
- g. Distributing and selling opioids prescribed by “pill mills” when Defendants knew or should have known the opioids were being prescribed by “pill mills;”
- h. Exacerbating the flood of opioids into Plaintiffs’ Community.

1423. Defendants intentionally and unreasonably distributed and sold opioids that Defendants knew would be diverted into the illegal, secondary market and would be obtained by persons with criminal purposes, and/or exacerbating and facilitated the flood of opioids in Plaintiffs’ Community.

1424. The Marketing Defendants intentionally and unreasonably engaged in a deceptive marketing scheme that was designed to, and successfully did, change the perception of opioids and cause their prescribing and sales to skyrocket in Plaintiffs’ Community.

1425. The Marketing Defendants intentionally and unreasonably misled Plaintiff, healthcare providers, and the public about the risks and benefits of opioids, including minimizing the risks of addiction and overdose and exaggerating the purported benefits of long-term use of opioids for the treatment of chronic pain.

1426. The Marketing Defendants violated West Virginia and federal statutes and regulations, including the controlled substances laws, by engaging in the deceptive marketing of opioids, as described in this Complaint.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

1427. Defendants are in the business of manufacturing, marketing, selling, distributing and/or facilitating the sale prescription drugs, including opioids, which are specifically known to Defendants to be dangerous because *inter alia* these drugs are defined under federal and state law as substances posing a high potential for abuse and addiction.

1428. Indeed, opioids are akin to medical grade heroin. Defendants' wrongful conduct of deceptively marketing and pushing as many opioids onto the market as possible led directly to the public nuisance and harm to Plaintiffs – exactly as would be expected when medical grade heroin in the form of prescription opioids are deceptively marketed, flood the community and are diverted into an illegal, secondary market.

1429. Defendants had control over their conduct in Plaintiffs' Community and that conduct has had an adverse effect on rights common to the general public. Marketing Defendants controlled their deceptive advertising and efforts to mislead the public, including their acts and omissions in detailing by their sales representatives, online communications, publications, Continuing Medical Education programs and other speaking events, and other means described in this Complaint. Defendants had control over their own shipments and sales of opioids and over their reporting, or lack thereof, of suspicious prescribers and orders. Supply Chain Defendants and National Pharmacies had control over their systems to prevent diversion (or lack thereof).

1430. Each of the Supply Chain Defendants controlled the systems they developed to prevent diversion, including whether and to what extent they trained their employees to report and halt suspicious orders, and whether they filled orders they knew or should have known were likely to be diverted or fuel an illegal market.

1431. PBMs had control of their promotion of opioids and preferential treatment of opioids.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

1432. National Pharmacies knew or should have known that their pharmacies in the Tri-State area were (a) filling multiple prescriptions to the same patient using the same doctor (b) filling multiple prescriptions by the same patient using different doctors (c) filling orders of unusual size and frequency for the same patient (d) filling orders of unusual size and frequency from out-of-state patients; (e) filling orders of unusual size and frequency paid for in cash (f) filling orders of unusual size and frequency from the same prescribing physician (g) filling orders of unusual size and frequency from out-of-state physicians, and should have used this information to prevent diversion.

1433. It was reasonably foreseeable that Defendants' actions and omissions would result in the public nuisance and harm to Plaintiffs described herein.

1434. Because of the Marketing Defendants' deceptive marketing of opioids and Defendants' special positions within the closed system of opioid distribution, without Defendants' actions, opioid use would not have become so widespread, and the enormous public health hazard of prescription opioid and heroin overuse, abuse, and addiction that now exists would have been averted.

1435. The public nuisance created by Defendants' actions is substantial and unreasonable. It has caused and continues to cause significant harm to Plaintiffs and Plaintiffs' Community and the harm inflicted outweighs any offsetting benefit.

1436. The externalized risks associated with Defendants' nuisance-creating conduct as described herein greatly exceed the internalized benefits.

1437. As a direct and proximate result of Defendants' tortious conduct and the public nuisance created by Defendants, Plaintiffs have suffered and will continue to suffer economic

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

damages including, but not limited to, significant expenses for police, emergency, health, prosecution, corrections, rehabilitation, and other services.

1438. As a direct and proximate result of Defendants' tortious conduct and the public nuisance created by Defendants, Plaintiffs have suffered and will continue to suffer stigma damage, non-physical property damage, and damage to its proprietary interests.

1439. The nuisance created by Defendants' conduct has not been abated.

1440. The nuisance created by Defendants' conduct is abatable.

1441. Defendants' misconduct alleged in this case is ongoing and persistent.

1442. Defendants' misconduct alleged in this case does not concern a discrete event or discrete emergency of the sort a political subdivision would reasonably expect to occur and is not part of the normal and expected costs of a local government's existence. Plaintiffs allege wrongful acts which are neither discrete nor of the sort a local government can reasonably expect.

1443. Plaintiffs have incurred expenditures for special programs over and above Plaintiffs' ordinary public services.

1444. Plaintiffs seek to abate the nuisance created by the Defendants' unreasonable, unlawful, intentional, ongoing, continuing, and persistent actions and omissions and unreasonable interference with rights common to the general public.

1445. Plaintiffs are asserting its own rights and interests and Plaintiffs' claims are not based upon or derivative of the rights of others.

1446. The tortious conduct of each Defendant was a substantial factor in creating the public nuisance.

1447. The tortious conduct of each Defendant was a substantial factor in producing harm to Plaintiffs.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

1448. Plaintiffs have suffered an indivisible injury as a result of the tortious conduct of Defendants.

1449. Defendants acted with actual malice because Defendants acted with a conscious disregard for the rights and safety of other persons, and said actions had a great probability of causing substantial harm.

1450. Plaintiffs seek all legal and equitable relief as allowed by law, including *inter alia* injunctive relief, restitution, disgorgement of profits, compensatory and punitive damages, and all damages allowed by law to be paid by the Defendants, attorney fees and costs, and pre and post-judgment interest.

SECOND CLAIM FOR RELIEF

**Violation of RICO, 18 U.S.C. § 1961 *et seq.* – Opioid Marketing Enterprise
(Against Defendants Purdue, Cephalon, Janssen, Endo, and Mallinckrodt (the “RICO
Marketing Defendants”))**

1451. Plaintiffs repeat, re-allege, and incorporate by reference each and every allegation set forth above as if fully set forth herein.

1452. The RICO Marketing Defendants—through the use of “Front Groups” that appeared to be independent of the RICO Marketing Defendants; through the dissemination of publications that supported the RICO Marketing Defendants’ scheme; through continuing medical education (“CME”) programs controlled and/or funded by the RICO Marketing Defendants; by the hiring and deployment of so-called “key opinion leaders,” (“KOLs”) who were paid by the RICO Marketing Defendants to promote their message; and through the “detailing” activities of the RICO Marketing Defendants’ sales forces—conducted an association-in-fact enterprise, and/or participated in the conduct of an enterprise through a pattern of illegal activities (the predicate racketeering acts of mail and wire fraud) to carry-out the common purpose of the Opioid Marketing Enterprise, i.e., to unlawfully increase profits and revenues from the continued

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

prescription and use of opioids for long-term chronic pain. Through the racketeering activities of the Opioid Marketing Enterprise sought to further the common purpose of the enterprise through a fraudulent scheme to change prescriber habits and public perception about the safety and efficacy of opioid use by convincing them that each of the nine false propositions alleged earlier were true. In so doing, each of the RICO Marketing Defendants knowingly conducted and participated in the conduct of the Opioid Marketing Activities by engaging in mail and wire fraud in violation of 18 U.S.C. §§ 1962(c) and (d).

1453. The Opioid Marketing Enterprise alleged above is an association-in-fact enterprise that consists of the RICO Marketing Defendants (Purdue Cephalon, Janssen, Endo, and Mallinckrodt); the Front Groups (APF, AAPM, APS, FSMB, USPF, and AGS); and the KOLs (Dr. Portenoy, Dr. Webster, Dr. Fine, and Dr. Fishman).

1454. Each of the RICO Marketing Defendants and the other members of the Opioid Marketing Enterprise conducted and participated in the conduct of the Opioid Marketing Enterprise by playing a distinct role in furthering the enterprise's common purpose of increasing profits and sales through the knowing and intentional dissemination of false and misleading information about the safety and efficacy of long-term opioid use, and the risks and symptoms of addiction, in order increase the market for prescription opioids by changing prescriber habits and public perceptions and increase the market for opioids.

1455. Specifically, the RICO Marketing Defendants each worked together to coordinate the enterprise's goals and conceal their role, and the enterprise's existence, from the public by, among other things, (i) funding, editing and distributing publications that supported and advanced their false messages; (ii) funding KOLs to further promote their false messages; (iii) funding, editing and distributing CME programs to advance their false messages; and (iv) tasking their own

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

employees to direct deceptive marketing materials and pitches directly at physicians and, in particular, at physicians lacking the expertise of pain care specialists (a practice known as sales detailing).

1456. Each of the Front Groups helped disguise the role of RICO Marketing Defendants by purporting to be unbiased, independent patient-advocacy and professional organizations in order to disseminate patient education materials, a body of biased and unsupported scientific “literature,” and “treatment guidelines” that promoted the RICO Marketing Defendants false messages.

1457. Each of the KOLs were physicians chosen and paid by each of the RICO Marketing Defendants to influence their peers’ medical practice by promoting the Marketing Defendants’ false message through, among other things, writing favorable journal articles and delivering supportive CMEs as if they were independent medical professionals, thereby further obscuring the RICO Marketing Defendants’ role in the enterprise and the enterprise’s existence.

1458. Further, each of the RICO Marketing Defendants, KOLs and Front Groups that made-up the Opioid Marketing Enterprise had systematic links to and personal relationships with each other through joint participation in lobbying groups, trade industry organizations, contractual relationships and continuing coordination of activities. The systematic links and personal relationships that were formed and developed allowed members of the Opioid Marketing Enterprise the opportunity to form the common purpose and agree to conduct and participate in the conduct of the Opioid Marketing Enterprise. Specifically each of the RICO Marketing Defendants coordinated their efforts through the same KOLs and Front Groups, based on their agreement and understanding that the Front Groups and KOLs were industry friendly and would work together with the RICO Marketing Defendants to advance the common purpose of the Opioid

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

Marketing Enterprise; each of the individuals and entities who formed the Opioid Marketing Enterprise acted to enable the common purpose and fraudulent scheme of the Opioid Marketing Enterprise.

1459. At all relevant times, the Opioid Marketing Enterprise: (a) had an existence separate and distinct from each RICO Marketing Defendant and its members; (b) was separate and distinct from the pattern of racketeering in which the RICO Marketing Defendants engaged; (c) was an ongoing and continuing organization consisting of individuals, persons, and legal entities, including each of the RICO Marketing Defendants; (d) was characterized by interpersonal relationships between and among each member of the Opioid Marketing Enterprise, including between the RICO Marketing Defendants and each of the Front Groups and KOLs; (e) had sufficient longevity for the enterprise to pursue its purpose and functioned as a continuing unit.

1460. The persons and entities engaged in the Opioid Marketing Enterprise are systematically linked through contractual relationships, financial ties, personal relationships, and continuing coordination of activities, as spearheaded by the RICO Marketing Defendants.

1461. The RICO Marketing Defendants conducted and participated in the conduct of the Opioid Marketing Enterprise through a pattern of racketeering activity that employed the use of mail and wire facilities, in violation of 18 U.S.C. § 1341 (mail fraud) and § 1343 (wire fraud), to increase profits and revenue by changing prescriber habits and public perceptions in order to increase the prescription and use of prescription opioids, and expand the market for opioids.

1462. The RICO Marketing Defendants each committed, conspired to commit, and/or aided and abetted in the commission of at least two predicate acts of racketeering activity (i.e. violations of 18 U.S.C. §§ 1341 and 1343) within the past ten years. The multiple acts of racketeering activity that the RICO Marketing Defendants committed, or aided and abetted in the

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

commission of, were related to each other, posed a threat of continued racketeering activity, and therefore constitute a “pattern of racketeering activity.” The racketeering activity was made possible by the RICO Marketing Defendants’ regular use of the facilities, services, distribution channels, and employees of the Opioid Marketing Enterprise, the U.S. Mail and interstate wire facilities. The RICO Marketing Defendants participated in the scheme to defraud by using mail, telephones and the Internet to transmit mailings and wires in interstate or foreign commerce.

1463. The RICO Marketing Defendants’ predicate acts of racketeering (18 U.S.C. § 1961(1)) include, but are not limited to:

- a. Mail Fraud: The RICO Marketing Defendants violated 18 U.S.C. § 1341 by sending or receiving, or by causing to be sent and/or received, materials via U.S. mail or commercial interstate carriers for the purpose of executing the unlawful scheme to design, manufacture, market, and sell the prescription opioids by means of false pretenses, misrepresentations, promises, and omissions.
- b. Wire Fraud: The RICO Marketing Defendants violated 18 U.S.C. § 1343 by transmitting and/or receiving, or by causing to be transmitted and/or received, materials by wire for the purpose of executing the unlawful scheme to design, manufacture, market, and sell the prescription opioids by means of false pretenses, misrepresentations, promises, and omissions.

1464. Indeed, as summarized herein, the RICO Marketing Defendants used the mail and wires to send or receive thousands of communications, publications, representations, statements, electronic transmissions and payments to carry-out the Opioid Marketing Enterprise’s fraudulent scheme.

1465. Because the RICO Marketing Defendants disguised their participation in the enterprise, and worked to keep even the enterprise’s existence secret so as to give the false appearance that their false messages reflected the views of independent third parties, many of the precise dates of the Opioid Marketing Enterprise’s uses of the U.S. Mail and interstate wire

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

facilities (and corresponding predicate acts of mail and wire fraud) have been hidden and cannot be alleged without access to the books and records maintained by the RICO Marketing Defendants, Front Groups, and KOLs. Indeed, an essential part of the successful operation of the Opioid Marketing Enterprise alleged herein depended upon secrecy. However, Plaintiffs have described the occasions on which the RICO Marketing Defendants, Front Groups, and KOLs disseminated misrepresentations and false statements to West Virginia consumers, prescribers, regulators and Plaintiff, and how those acts were in furtherance of the scheme.

1466. Each instance of racketeering activity alleged herein was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, including West Virginia consumers, prescribers, regulators and Plaintiff. The RICO Marketing Defendants, Front Groups and KOLs calculated and intentionally crafted the scheme and common purpose of the Opioid Marketing Enterprise to ensure their own profits remained high. In designing and implementing the scheme, the RICO Marketing Defendants understood and intended that those in the distribution chain rely on the integrity of the pharmaceutical companies and ostensibly neutral third parties to provide objective and scientific evidence regarding the RICO Marketing Defendants' products.

1467. The RICO Marketing Defendants' pattern of racketeering activity alleged herein and the Opioid Marketing Enterprise are separate and distinct from each other. Likewise, the RICO Marketing Defendants are distinct from the Opioid Marketing Enterprise.

1468. The pattern of racketeering activity alleged herein is continuing as of the date of this complaint, and, upon information and belief, will continue into the future unless enjoined by this Court.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

1469. The racketeering activities conducted by the RICO Marketing Defendants, Front Groups and KOLs amounted to a common course of conduct, with a similar pattern and purpose, intended to deceive West Virginia consumers, prescribers, regulators and the Plaintiff. Each separate use of the U.S. Mail and/or interstate wire facilities employed by Defendants was related, had similar intended purposes, involved similar participants and methods of execution, and had the same results affecting the same victims, including West Virginia consumers, prescribers, regulators and the Plaintiff. The RICO Marketing Defendants have engaged in the pattern of racketeering activity for the purpose of conducting the ongoing business affairs of the Opioid Marketing Enterprise.

1470. Each of the RICO Marketing Defendants aided and abetted others in the violations of the above laws, thereby rendering them indictable as principals in the 18 U.S.C. §§ 1341 and 1343 offenses.

1471. As described herein, the RICO Marketing Defendants engaged in a pattern of related and continuous predicate acts for years. The predicate acts constituted a variety of unlawful activities, each conducted with the common purpose of obtaining significant money and revenue from the marketing and sale of their highly addictive and dangerous drugs. The predicate acts also had the same or similar results, participants, victims, and methods of commission. The predicate acts were related and not isolated events.

1472. The pattern of racketeering activity alleged herein is continuing as of the date of this Complaint and, upon information and belief, will continue into the future unless enjoined by this Court. The last racketeering incident occurred within five years of the commission of a prior incident of racketeering.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

1473. The RICO Marketing Defendants' violations of law and their pattern of racketeering activity directly and proximately caused Plaintiffs injury in Plaintiffs' business and property. The RICO Marketing Defendants' pattern of racketeering activity logically, substantially and foreseeably caused an opioid epidemic. Plaintiffs' injuries, as described below, were not unexpected, unforeseen or independent.⁶¹² Rather, as Plaintiffs allege, the RICO Marketing Defendants knew that the opioids were unsuited to treatment of long-term chronic, non-acute, and non-cancer pain, or for any other use not approved by the FDA, and knew that opioids were highly addictive and subject to abuse.⁶¹³ Nevertheless, the RICO Marketing Defendants engaged in a scheme of deception that utilized the mail and wires in order to carry-out the Opioid Marketing Enterprises' fraudulent scheme, thereby increasing sales of their opioid products.

1474. It was foreseeable and expected that the RICO Marketing Defendants creating and then participating in the Opioid Marketing Enterprise through a pattern of racketeering activities to carry-out their fraudulent scheme would lead to a nationwide opioid epidemic, including increased opioid addiction and overdose.⁶¹⁴

1475. Specifically, the RICO Marketing Defendants' creation of, and then participation in, the Opioid Marketing Enterprise through a pattern of racketeering activities to carry-out their fraudulent scheme has injured Plaintiffs in the form of substantial losses of money and property that logically, directly and foreseeably arise from the opioid-addiction epidemic. Plaintiffs' injuries, as alleged throughout this complaint, and expressly incorporated herein by reference, include:

- a. Losses caused by the decrease in funding available for Plaintiffs' public services for which funding was lost because it was diverted to other public services designed to address the opioid epidemic;

⁶¹² *Travelers Prop. Cas. Co. of Am. v. Actavis, Inc.*, 16 Cal. App. 5th 1026 (2017).

⁶¹³ *Id.*

⁶¹⁴ *Id.*

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

- b. Costs for providing healthcare and medical care, additional therapeutic, and prescription drug purchases, and other treatments for patients suffering from opioid-related addiction or disease, including overdoses and deaths;
- c. Costs of training emergency and/or first responders in the proper treatment of drug overdoses;
- d. Costs associated with providing police officers, firefighters, and emergency and/or first responders with naloxone—an opioid antagonist used to block the deadly effects of opioids in the context of overdose;
- e. Costs associated with emergency responses by police officers, firefighters, and emergency and/or first responders to opioid overdoses;
- f. Costs for providing mental-health services, treatment, counseling, rehabilitation services, and social services to victims of the opioid epidemic and their families;
- g. Costs for providing treatment of infants born with opioid-related medical conditions, or born addicted to opioids due to drug use by mother during pregnancy;
- h. Costs associated with law enforcement and public safety relating to the opioid epidemic, including but not limited to attempts to stop the flow of opioids into local communities, to arrest and prosecute street-level dealers, to prevent the current opioid epidemic from spreading and worsening, and to deal with the increased levels of crimes that have directly resulted from the increased homeless and drug-addicted population;
- i. Costs associated with increased burden on Plaintiff's judicial system, including increased security, increased staff, and the increased cost of adjudicating criminal matters due to the increase in crime directly resulting from opioid addiction;
- j. Costs associated with providing care for children whose parents suffer from opioid-related disability or incapacitation;
- k. Loss of tax revenue due to the decreased efficiency and size of the working population in Plaintiffs' Community;
- l. Losses caused by diminished property values in neighborhoods where the opioid epidemic has taken root; and
- m. Losses caused by diminished property values in the form of decreased business investment and tax revenue.

1476. Plaintiff's injuries were directly and thus proximately caused by these Defendants' racketeering activities because they were the logical, substantial and foreseeable cause of Plaintiff's injuries. But for the opioid-addiction epidemic the RICO Marketing Defendants created through their Opioid Marketing Enterprise, Plaintiff would not have lost money or property.

1477. Plaintiffs are the most directly harmed entity and there is no other Plaintiff better suited to seek a remedy for the economic harms at issue here.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

1478. Plaintiffs seek all legal and equitable relief as allowed by law, including, *inter alia*, actual damages; treble damages; equitable and/or injunctive relief in the form of court-supervised corrective communication, actions and programs; forfeiture as deemed proper by the Court; attorney's fees; all costs and expenses of suit; and pre- and post-judgment interest, including, *inter alia*:

- a. Actual damages and treble damages, including pre-suit and post-judgment interest;
- b. An order enjoining any further violations of RICO;
- c. An order enjoining any further violations of any statutes alleged to have been violated in this Complaint;
- d. An order enjoining the commission of any tortious conduct, as alleged in this Complaint;
- e. An order enjoining any future marketing or misrepresentations regarding the health benefits or risks of prescription opioids use, except as specifically approved by the FDA;
- f. An order enjoining any future marketing of opioids through non-branded marketing including through the Front Groups, KOLs, websites, or in any other manner alleged in this Complaint that deviates from the manner or method in which such marketing has been approved by the FDA;
- g. An order enjoining any future marketing to vulnerable populations, including but not limited to, persons over the age of fifty-five, anyone under the age of twenty-one, and veterans;
- h. An order compelling the Defendants to make corrective advertising statements that shall be made in the form, manner and duration as determined by the Court, but not less than print advertisements in national and regional newspapers and medical journals, televised broadcast on major television networks, and displayed on their websites, concerning: (1) the risk of addiction among patients taking opioids for pain; (2) the ability to manage the risk of addiction; (3) pseudoaddiction is really addiction, not a sign of undertreated addiction; (4) withdrawal from opioids is not easily managed; (5) increasing opioid dosing presents significant risks, including addiction and overdose; (6) long term use of opioids has no demonstrated improvement of function; (8) use of time-released opioids does not prevent addiction; (9) abuse-

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

deterrent formulations do not prevent opioid abuse; and (10) that manufacturers and distributors have duties under the CSA to monitor, identify, investigate, report and halt suspicious orders and diversion but failed to do so;

- i. An order enjoining any future lobbying or legislative efforts regarding the manufacturer, marketing, distribution, diversion, prescription, or use of opioids;
- j. An order requiring all Defendants to publicly disclose all documents, communications, records, data, information, research or studies concerning the health risks or benefits of opioid use;
- k. An order prohibiting all Defendants from entering into any new payment or sponsorship agreement with, or related to, any: Front Group, trade association, doctor, speaker, CME, or any other person, entity, or association, regarding the manufacturer, marketing, distribution, diversion, prescription, or use of opioids;
- l. An order establishing a National Foundation for education, research, publication, scholarship, and dissemination of information regarding the health risks of opioid use and abuse to be financed by the Defendants in an amount to be determined by the Court;
- m. An order enjoining any diversion of opioids or any failure to monitor, identify, investigate, report and halt suspicious orders or diversion of opioids;
- n. An order requiring all Defendants to publicly disclose all documents, communications, records, information, or data, regarding any prescriber, facility, pharmacy, clinic, hospital, manufacturer, distributor, person, entity or association regarding suspicious orders for or the diversion of opioids;
- o. An order divesting each Defendant of any interest in, and the proceeds of any interest in, the Marketing and Supply Chain Enterprises, including any interest in property associated with the Marketing and Supply Chain Enterprises;
- p. Dissolution and/or reorganization of any trade industry organization, Front Group, or any other entity or association associated with the Marketing and Supply Chain Enterprises identified in this Complaint, as the Court sees fit;
- q. Dissolution and/or reorganization of any Defendant named in this Complaint as the Court sees fit;

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

- r. Suspension and/or revocation of the license, registration, permit, or prior approval granted to any Defendant, entity, association or enterprise named in the Complaint regarding the manufacture or distribution of opioids;
- s. Forfeiture as deemed appropriate by the Court; and
- t. Attorney's fees and all costs and expenses of suit.

THIRD CLAIM FOR RELIEF

**Violation of RICO, 18 U.S.C. § 1961 *et seq.* – Opioid Supply Chain Enterprise
(Against Defendants Purdue, Cephalon, Endo, Mallinckrodt, Actavis, McKesson, Cardinal Health, and AmerisourceBergen (the “RICO Supply Chain Defendants”))**

1479. Plaintiffs repeat, re-allege, and incorporate by reference each and every allegation set forth above as if fully set forth herein.

1480. At all relevant times, the RICO Supply Chain Defendants were and are “persons” under 18 U.S.C. § 1961(3) because they are entities capable of holding, and do hold, “a legal or beneficial interest in property.”

1481. The RICO Supply Chain Defendants together formed an association-in-fact enterprise, the Opioid Supply Chain Enterprise, for the purpose of increasing the quota for and profiting from the increased volume of opioid sales in the United States. The Opioid Supply Chain Enterprise is an association-in-fact enterprise within the meaning of § 1961. The Opioid Supply Chain Enterprise consists of the RICO Supply Chain Defendants.

1482. The RICO Supply Chain Defendants were members the Healthcare Distribution Alliance (the “HDA”).⁶¹⁵ Each of the RICO Supply Chain Defendants is a member, participant, and/or sponsor of the HDA, and has been since at least 2006, and utilized the HDA to form the

⁶¹⁵ *History*, Health Distribution Alliance, (last accessed on September 15, 2017), <https://www.healthcaredistribution.org/about/hda-history>.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

interpersonal relationships of the Opioid Supply Chain Enterprise and to assist them in engaging in the pattern of racketeering activity that gives rise to the Count.

1483. At all relevant times, the Opioid Supply Chain Enterprise: (a) had an existence separate and distinct from each of the RICO Supply Chain Defendants; (b) was separate and distinct from the pattern of racketeering in which the RICO Supply Chain Defendants engaged; (c) was an ongoing and continuing organization consisting of legal entities, including each of the RICO Supply Chain Defendants; (d) was characterized by interpersonal relationships among the RICO Supply Chain Defendants; (e) had sufficient longevity for the enterprise to pursue its purpose; and (f) functioned as a continuing unit. Each member of the Opioid Supply Chain Enterprise participated in the conduct of the enterprise, including patterns of racketeering activity, and shared in the astounding growth of profits supplied by fraudulently inflating opioid quotas and resulting sales.

1484. The RICO Supply Chain Defendants carried out, or attempted to carry out, a scheme to defraud federal and state regulators, and the American public by knowingly conducting or participating in the conduct of the Opioid Supply Chain Enterprise through a pattern of racketeering activity within the meaning of 18 U.S.C. § 1961(1) that employed the use of mail and wire facilities, in violation of 18 U.S.C. § 1341 (mail fraud) and § 1343 (wire fraud).

1485. The RICO Supply Chain Defendants committed, conspired to commit, and/or aided and abetted in the commission of at least two predicate acts of racketeering activity (*i.e.* violations of 18 U.S.C. §§ 1341 and 1343) within the past ten years. The multiple acts of racketeering activity that the RICO Supply Chain Defendants committed, or aided and abetted in the commission of, were related to each other, posed a threat of continued racketeering activity, and therefore constitute a “pattern of racketeering activity.” The racketeering activity was made possible by the

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

RICO Supply Chain Defendants' regular use of the facilities, services, distribution channels, and employees of the Opioid Supply Chain Enterprise. The RICO Supply Chain Defendants participated in the scheme to defraud by using mail, telephone and the Internet to transmit mailings and wires in interstate or foreign commerce.

1486. The RICO Supply Chain Defendants also conducted and participated in the conduct of the affairs of the Opioid Supply Chain Enterprise through a pattern of racketeering activity by the felonious manufacture, importation, receiving, concealment, buying, selling, or otherwise dealing in a controlled substance or listed chemical (as defined in section 102 of the Controlled Substance Act), punishable under any law of the United States.

1487. The RICO Supply Chain Defendants committed crimes that are punishable as felonies under the laws of the United States. Specifically, 21 U.S.C. § 843(a)(4) makes it unlawful for any person to knowingly or intentionally furnish false or fraudulent information in, or omit any material information from, any application, report, record or other document required to be made, kept or filed under this subchapter. A violation of § 843(a)(4) is punishable by up to four years in jail, making it a felony. 21 U.S.C. § 843(d)(1).

1488. Each of the RICO Supply Chain Defendants is a registrant as defined in the CSA. Their status as registrants under the CSA requires that they maintain effective controls against diversion of controlled substances in schedule I or II, design and operate a system to disclose to the registrant suspicious orders of controlled substances and inform the DEA of suspicious orders when discovered by the registrant. 21 U.S.C. § 823; 21 C.F.R. § 1301.74(b).

1489. The RICO Supply Chain Defendants' predicate acts of racketeering (18 U.S.C. § 1961(1)) include, but are not limited to:

- a. Mail Fraud: The RICO Supply Chain Defendants violated 18 U.S.C. § 1341 by sending or receiving, or by causing to be sent and/or received,

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

materials via U.S. mail or commercial interstate carriers for the purpose of executing the unlawful scheme to design, manufacture, market, and sell the prescription opioids by means of false pretenses, misrepresentations, promises, and omissions.

- b. Wire Fraud: The RICO Supply Chain Defendants violated 18 U.S.C. § 1343 by transmitting and/or receiving, or by causing to be transmitted and/or received, materials by wire for the purpose of executing the unlawful scheme to design, manufacture, market, and sell the prescription opioids by means of false pretenses, misrepresentations, promises, and omissions.
- c. Controlled Substance Violations: The RICO Supply Chain Defendants violated 21 U.S.C. § 843 by knowingly or intentionally furnishing false or fraudulent information in, and/or omitting material information from, documents filed with the DEA.

1490. The RICO Supply Chain Defendants conducted their pattern of racketeering activity in this jurisdiction and throughout the United States through this enterprise.

1491. The RICO Supply Chain Defendants aided and abetted others in the violations of the above laws, thereby rendering them indictable as principals in the 18 U.S.C. §§ 1341 and 1343 offenses.

1492. The RICO Supply Chain Defendants hid from the general public and suppressed and/or ignored warnings from third parties, whistleblowers and governmental entities about the reality of the suspicious orders that the RICO Supply Chain Defendants were filling on a daily basis – leading to the diversion of hundreds of millions of doses of prescriptions opioids into the illicit market.

1493. The RICO Supply Chain Defendants, with knowledge and intent, agreed to the overall objective of their fraudulent scheme and participated in the common course of conduct to commit acts of fraud and indecency in manufacturing and distributing prescription opioids.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

1494. Indeed, for the Defendants' fraudulent scheme to work, each of the Defendants had to agree to implement similar tactics regarding manufacturing prescription opioids and refusing to report suspicious orders.

1495. As described herein, the RICO Supply Chain Defendants engaged in a pattern of related and continuous predicate acts for years. The predicate acts constituted a variety of unlawful activities, each conducted with the common purpose of obtaining significant monies and revenues from the sale of their highly addictive and dangerous drugs. The predicate acts also had the same or similar results, participants, victims, and methods of commission. The predicate acts were related and not isolated events.

1496. The predicate acts all had the purpose of creating the opioid epidemic that substantially injured Plaintiffs' business and property, while simultaneously generating billion-dollar revenue and profits for the RICO Supply Chain Defendants. The predicate acts were committed or caused to be committed by the RICO Supply Chain Defendants through their participation in the Opioid Supply Chain Enterprise and in furtherance of its fraudulent scheme.

1497. The pattern of racketeering activity alleged herein and the Opioid Supply Chain Enterprise are separate and distinct from each other. Likewise, the RICO Supply Chain Defendants are distinct from the enterprise.

1498. The pattern of racketeering activity alleged herein is continuing as of the date of this Complaint and, upon information and belief, will continue into the future unless enjoined by this Court.

1499. Many of the precise dates of the RICO Supply Chain Defendants' criminal actions at issue here have been hidden by Defendants and cannot be alleged without access to Defendants'

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

books and records. Indeed, an essential part of the successful operation of the Opioid Supply Chain Enterprise alleged herein depended upon secrecy.

1500. By intentionally refusing to report and halt suspicious orders of their prescription opioids, Defendants engaged in a fraudulent scheme and unlawful course of conduct constituting a pattern of racketeering activity.

1501. It was foreseeable to the RICO Supply Chain Defendants that Plaintiffs would be harmed when they refused to report and halt suspicious orders, because their violation of the duties imposed by the CSA and Code of Federal Regulations allowed the widespread diversion of prescription opioids out of appropriate medical channels and into the illicit drug market – causing the opioid epidemic that the CSA intended to prevent.

1502. The last racketeering incident occurred within five years of the commission of a prior incident of racketeering.

1503. The RICO Supply Chain Defendants' violations of law and their pattern of racketeering activity directly and proximately caused Plaintiffs' injury in its business and property. The RICO Supply Chain Defendants' pattern of racketeering activity, including their refusal to identify, report and halt suspicious orders of controlled substances, logically, substantially and foreseeably cause an opioid epidemic. Plaintiffs were injured by the RICO Supply Chain Defendants' pattern of racketeering activity and the opioid epidemic that they created.

1504. The RICO Supply Chain Defendants knew that the opioids they manufactured and supplied were unsuited to treatment of long-term, chronic, non-acute, and non-cancer pain, or for any other use not approved by the FDA, and knew that opioids were highly addictive and subject to abuse.⁶¹⁶ Nevertheless, the RICO Supply Chain Defendants engaged in a scheme of deception,

⁶¹⁶ *Travelers Prop. Cas. Co. of Am. v. Actavis, Inc.*, 16 Cal. App. 5th 1026 (2017)..

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

that utilized the mail and wires as part of their fraud, in order to increase sales of their opioid products by refusing to identify, report suspicious orders of prescription opioids that they knew were highly addictive, subject to abuse, and were actually being diverted into the illegal market.⁶¹⁷

1505. The RICO Supply Chain Defendants' predicate acts and pattern of racketeering activity were a cause of the opioid epidemic which has injured Plaintiffs in the form of substantial losses of money and property that logically, directly and foreseeably arise from the opioid-addiction epidemic.

1506. Specifically, Plaintiffs' injuries, as alleged throughout this complaint, and expressly incorporated herein by reference, include:

- a. Losses caused by the decrease in funding available for Plaintiffs' public services for which funding was lost because it was diverted to other public services designed to address the opioid epidemic;
- b. Costs for providing healthcare and medical care, additional therapeutic, and prescription drug purchases, and other treatments for patients suffering from opioid-related addiction or disease, including overdoses and deaths;
- c. Costs of training emergency and/or first responders in the proper treatment of drug overdoses;
- d. Costs associated with providing police officers, firefighters, and emergency and/or first responders with naloxone – an opioid antagonist used to block the deadly effects of opioids in the context of overdose;
- e. Costs associated with emergency responses by police officers, firefighters, and emergency and/or first responders to opioid overdoses;
- f. Costs for providing mental-health services, treatment, counseling, rehabilitation services, and social services to victims of the opioid epidemic and their families;
- g. Costs for providing treatment of infants born with opioid-related medical conditions, or born addicted to opioids due to drug use by mother during pregnancy;
- h. Costs associated with law enforcement and public safety relating to the opioid epidemic, including but not limited to attempts to stop the flow of opioids into local communities, to arrest and prosecute street-level dealers, to prevent the

⁶¹⁷ *City of Everett v. Purdue Pharma L.P.*, 2017 WL 4236062, *6 (W.D. Wash. Sept. 25, 2017).

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

current opioid epidemic from spreading and worsening, and to deal with the increased levels of crimes that have directly resulted from the increased homeless and drug-addicted population;

- i. Costs associated with increased burden on Plaintiffs' judicial system, including increased security, increased staff, and the increased cost of adjudicating criminal matters due to the increase in crime directly resulting from opioid addiction;
- j. Costs associated with providing care for children whose parents suffer from opioid-related disability or incapacitation;
- k. Loss of tax revenue due to the decreased efficiency and size of the working population in Plaintiffs' Community;
- l. Losses caused by diminished property values in neighborhoods where the opioid epidemic has taken root; and
- m. Losses caused by diminished property values in the form of decreased business investment and tax revenue.

1507. Plaintiffs' injuries were proximately caused by Defendants' racketeering activities because they were the logical, substantial and foreseeable cause of Plaintiffs' injuries. But for the opioid-addiction epidemic created by Defendants' conduct, Plaintiffs would not have lost money or property.

1508. Plaintiffs' injuries were directly caused by the RICO Supply Chain Defendants' pattern of racketeering activities.

1509. Plaintiffs are most directly harmed and there are no other plaintiffs better suited to seek a remedy for the economic harms at issue here.

1510. Plaintiffs seek all legal and equitable relief as allowed by law, including, *inter alia*, actual damages; treble damages; equitable and/or injunctive relief in the form of court-supervised corrective communication, actions and programs; forfeiture as deemed proper by the Court; attorney's fees; all costs and expenses of suit; and pre- and post-judgment interest, and all of the relief sought into the First Claim for Relief, as the Court deems just and applicable.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

FOURTH CLAIM FOR RELIEF

**Negligence
(Against Supply Chain Defendants)**

1511. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein, and further alleges

1512. Defendants owed Plaintiffs a duty to not expose Plaintiffs to an unreasonable risk of harm.

1513. Defendants had a legal duty to exercise reasonable and ordinary care and skill in accordance with applicable standards of conduct in manufacturing, advertising, marketing, selling, distributing, and or facilitating the sale of opioids.

1514. Supply Chain Defendants had a duty not to breach the standard of care established under West Virginia law and regulations and the CSA and its implementing regulations to report suspicious prescribing and to maintain systems to detect and report such activity.⁶¹⁸

1515. Supply Chain Defendants had a duty to maintain systems to effectively prevent diversion under the standard of care established under West Virginia law and regulations and the CSA. *Id.*

1516. The degree of care the law requires is commensurate with the risk of harm the conduct creates. Defendants' conduct in marketing, distributing, selling, and facilitating the sale of dangerously addictive drugs requires a high degree of care and places them in a position of great trust and responsibility vis a vis Plaintiff. Their duty cannot be delegated.

⁶¹⁸ See 21 U.S.C. §823; 21 C.F.R. 1301.74; W. Va. C.S.R. § 15- 2-4.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

1517. Each Defendant breached its duty to exercise the degree of care, prudence, watchfulness, and vigilance commensurate with the dangers involved in selling dangerous controlled substances.

1518. Defendants breached their duty to Plaintiffs by, *inter alia*:

- a. Distributing and selling opioids in ways that facilitated and encouraged their flow into the illegal, secondary market;
- b. Distributing and selling opioids without maintaining effective controls against the diversion of opioids;
- c. Choosing not to effectively monitor for suspicious orders;
- d. Choosing not to investigate suspicious orders;
- e. Choosing not to report suspicious orders;
- f. Choosing not to stop or suspend shipments of suspicious orders; and
- g. Distributing and selling opioids prescribed by “pill mills” when Defendants knew or should have known the opioids were being prescribed by “pill mills.”

1519. The Marketing Defendants breached their duty to Plaintiffs by deceptively marketing opioids, including minimizing the risks of addiction and overdose and exaggerating the purported benefits of long-term use of opioids for the treatment of chronic pain.

1520. Defendants engaged in conduct the foreseeable result of which was to cause harm to Plaintiff.

1521. Defendants have engaged in affirmative acts of creating an illegal, secondary prescription opioid market by failing to exercise adequate control over the marketing, distribution and sale of their prescription opioids.

1522. Defendants were negligent by marketing, distributing, selling, and facilitating the flood of opioids in a way that created and fostered an illegal, secondary prescription opioid market that resulted in a foreseeable and unreasonable risk of harm to Plaintiff.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

1523. The method by which Defendants created this market was by marketing, distributing, selling, and facilitating the sale opioids without regard to the likelihood that the opioids would be placed in the hands of criminals, addicts, juveniles, and others not permitted to use or possess prescription opioids.

1524. A reasonably prudent opioid manufacturer and distributor should have anticipated an injury to Plaintiffs as a probable result of marketing, distributing, selling, and facilitating the sale of prescription opioids in this manner.

1525. It was reasonably foreseeable that Defendants' actions and omissions would result in the harm to Plaintiffs as described herein.

1526. Defendants had control over their conduct in Plaintiffs' Community. Marketing Defendants controlled their deceptive advertising and efforts to mislead the public, including their acts and omissions in detailing by their sales representatives, online communications, publications, Continuing Medical Education programs and other speaking events, and other means described in this Complaint. Defendants had control over their own shipments of opioids and over their reporting, or lack thereof, of suspicious prescribers and orders. Each of the Defendants controlled any of the systems they developed to prevent diversion, including the criteria and process they used to identify suspicious orders, whether and to what extent they trained their employees to report and halt suspicious orders, and whether they filled orders they knew or should have known were likely to be diverted or fuel an illegal market.

1527. Because of the Marketing Defendants' deceptive marketing of opioids and each of the Defendants' special positions within the closed system of opioid sale and distribution, without Defendants' actions, opioid use would not have become so widespread, and the enormous public

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

health hazard of prescription opioid and heroin overuse, abuse, and addiction that now exists would have been averted.

1528. Defendants also misleadingly portrayed themselves as cooperating with law enforcement and actively working to combat the opioid epidemic when, in reality, Defendants failed to satisfy even their minimum, legally required obligations – including the Supply Chain Defendants' obligation to report suspicious orders. Defendants voluntarily undertook duties, through their statements to the media, regulators, and the public at large, to take all reasonable precautions to prevent drug diversion.

1529. Defendants are in the business of manufacturing, marketing, selling, distributing, and/or facilitating the sale of prescription drugs, including opioids, which are specifically known to Defendants to be dangerous because *inter alia* these drugs are defined under federal and state law as substances posing a high potential for abuse and addiction.

1530. Indeed, opioids are akin to medical grade heroin. Defendants' wrongful conduct of deceptively marketing and pushing as many opioids onto the market as possible led directly to the public nuisance and harm to Plaintiffs—exactly as would be expected when medical grade heroin in the form of prescription opioids are deceptively marketed, flood the community, and are diverted into an illegal, secondary market.

1531. Reasonably prudent manufacturers, distributors, and purveyors of prescription opioids would have anticipated that the scourge of opioid addiction would wreak havoc on communities, and the significant costs which would be imposed upon the governmental entities associated with those communities.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

1532. The Supply Chain Defendants were required under West Virginia law to first be licensed by the West Virginia State Board of Pharmacy.⁶¹⁹

1533. To receive and maintain their license, each of the Distributor Defendants has a duty to comply with federal, state, and local laws regarding the distribution of drugs.⁶²⁰

1534. The West Virginia State Board of Pharmacy has the authority to suspend or revoke licenses or registrations issued to Distributors who violate Board of Pharmacy regulations.⁶²¹

1535. Federal and West Virginia laws and regulations require Supply Chain Defendants to act as gatekeepers guarding against the diversion of the highly addictive, dangerous opioid drugs.⁶²²

1536. The federal mandates incorporated into West Virginia law require that Supply Chain Defendants must maintain “effective control against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels.”⁶²³ These federal regulations impose a non-delegable duty upon both manufacturers and distributors to “design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant [distributor or manufacturer] shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.”⁶²⁴

⁶¹⁹ W. Va. Code § 60A-8-7.

⁶²⁰ W. Va. Code § 60A-8-7(c)(1)(I); see also W. Va. Code § 60A-8-7(c)(3) (requiring compliance with guidelines adopted by the United States Food and Drug Administration).

⁶²¹ W. Va. Code § 60A-8-10(c).

⁶²² See 21 U.S.C. § 823; 21 C.F.R. 1301.74; 21 C.F.R. 1301.71; W. Va. C.S.R. § 15- 2-4.

⁶²³ 21 U.S.C. §§ 823(a)(1), (b)(1).

⁶²⁴ 21 C.F.R. § 1301.74(b).

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

1537. In addition to reporting all suspicious orders, Supply Chain Defendants must also stop shipment on any order which is flagged as suspicious and only ship orders which were flagged as potentially suspicious if, after conducting due diligence, the distributor can determine that the order is not likely to be diverted into illegal channels.⁶²⁵ Regardless, all flagged orders must be reported. *Id.*

1538. Supply Chain Defendants also violated section 60A-4-401(a) of the West Virginia Uniform Controlled Substances Act, which provides that, “Except as authorized by this act, it is unlawful for any person any person to manufacture, deliver, or possess with intent to manufacture or deliver a controlled substance.”

1539. Supply Chain Defendants’ actions were not “authorized” by the West Virginia Uniform Controlled Substances Act because Defendants did not comply with the mandatory terms of the licenses issued to them by the West Virginia Board of Pharmacy or with federal requirements incorporated by reference, as further detailed in this Complaint.

1540. Supply Chain Defendants also violated the West Virginia Board of Pharmacy Regulations which requires that “all registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances.”⁶²⁶

1541. Additionally, the Supply Chain Defendants violated the regulation which requires “the registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Office of the Board of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders

⁶²⁵ See *Southwood Pharm., Inc.*, 72 Fed. Reg. 36,487, 36,501 (Drug Enf’t Admin. July 3, 2007); *Masters Pharm., Inc. v. Drug Enf’t Admin.*, 861 F.3d 206 (D.C. Cir. 2017).

⁶²⁶ W. Va. C.S.R. §15-2-4.2.1.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

deviating substantially from a normal pattern, and orders of unusual frequency.”⁶²⁷ Defendants also violated the regulation which requires “the registrant shall notify the Office of the Board of any theft or significant loss of any controlled substances upon discovery of the theft or loss as provided in subsection 8.3.”⁶²⁸

1542. Plaintiffs are within the class intended to be protected by the public safety statutes and regulations concerning controlled substances.

1543. Defendants’ violations of these public safety laws are *prima facie* evidence of negligence per se.⁶²⁹ Each Defendant had a duty under *inter alia* these laws to maintain effective controls against diversion of prescription opioids and to guard against, prevent, and report suspicious orders of opioids. Defendants’ violations of the law constitute negligence per se. Defendants breached mandatory, non-delegable legal duties and did not act reasonably under the circumstances.

1544. West Virginia law recognizes that these violations of statutes constitute *prima facie* evidence of negligence.⁶³⁰

1545. Marketing Defendants knew or should have known, that their affirmative misconduct in engaging in an aggressive, widespread, and misleading campaign in marketing narcotic drugs created an unreasonable risk of harm. The Defendants’ sales data, reports from sales representatives, and internal documents, should have put them on notice that such harm was not only foreseeable, but was actually occurring. Defendants nevertheless chose to deceptively

⁶²⁷ W. Va. C.S.R. §15-2-4.4.

⁶²⁸ W. Va. C.S.R. §15-2-4.5.

⁶²⁹ See *Waugh v. Traxler*, 186 W.Va. 355, 412 S.E.2d 756, (1991).

⁶³⁰ Syl. pt. 1, *Anderson v. Moulder*, 183 W.Va. 77, 394 S.E.2d 61 (1990); see also W.Va. Code § 55-7-9 (“Any person injured by the violation of any statute may recover from the offender such damages as he may sustain by reason of the violation...”).

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

withhold information about the dangers of opioids from Plaintiff, physicians, patients, and the public.

1546. Defendants' conduct was negligence *per se* in that Defendants violated federal law, including, but not limited to, 21 U.S.C. §§ 823 and 827(d)(1); 21 C.F.R. §§ 1301.74, 1304.21, 1304.22, and 1304.33(e); and West Virginia law, including, but not limited to, W. Va. Code § 60A-8-7(c)(1)(I); W. Va. Code § 60A-8-7(c)(3); W. Va. C.S.R. § 15- 2-4. Plaintiffs were parties intended to be protected by such laws and whose injuries said laws were designed to prevent. Defendants' violations of said laws proximately caused injury to Plaintiffs.

1547. Defendants also violated federal and West Virginia statutes and regulations, including the controlled substances laws, by, *inter alia*:

- a. Distributing and selling opioids in ways that facilitated and encouraged their flow into the illegal, secondary market;
- b. Distributing and selling opioids without maintaining effective controls against the diversion of opioids;
- c. Choosing not to effectively monitor for suspicious orders;
- d. Choosing not to investigate suspicious orders;
- e. Choosing not to report suspicious orders;
- f. Choosing not to stop or suspend shipments of suspicious orders; and
- g. Distributing and selling opioids prescribed by "pill mills" when Defendants knew or should have known the opioids were being prescribed by "pill mills."
- h. Facilitating the sale and flood of opioids into Plaintiffs' Community.

1548. As a direct and proximate result of Defendants' negligence and/or negligence *per se*, Plaintiffs have suffered and will continue to suffer economic damages including, but not limited to, significant expenses for police, emergency, health, prosecution, corrections, rehabilitation, and other services.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

1549. As a direct and proximate result of Defendants' negligence and/or negligence *per se*, Plaintiffs have suffered and will continue to suffer stigma damage, non-physical property damage, and damage to its proprietary interests.

1550. As a direct and proximate result of Defendants' negligent, willful, wanton, and intentional acts, omissions, misrepresentations and otherwise culpable acts, there is now a national opioid epidemic that has caused enormous harm and injury to the Plaintiffs and Plaintiffs' Community.

1551. Defendants' misconduct alleged in this case is ongoing and persistent.

1552. Defendants' misconduct alleged in this case does not concern a discrete event or discrete emergency of the sort a political subdivision would reasonably expect to occur and is not part of the normal and expected costs of a local government's existence. Plaintiffs allege wrongful acts which are neither discrete nor of the sort a local government can reasonably expect.

1553. Plaintiffs have incurred expenditures for special programs over and above Plaintiffs' ordinary public services.

1554. Plaintiffs have suffered an indivisible injury as a result of the tortious conduct of Defendants.

1555. The tortious conduct of each Defendant was a substantial factor in producing harm to Plaintiffs.

1556. Defendants acted with actual malice because Defendants acted with a conscious disregard for the rights and safety of other persons, and said actions have a great probability of causing substantial harm.

1557. Plaintiffs seek all legal and equitable relief as allowed by law, including *inter alia* injunctive relief, restitution, disgorgement of profits, compensatory and punitive damages, and all

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

damages allowed by law to be paid by the Defendants, attorney fees and costs, and pre- and post-judgment interest.

FIFTH CLAIM FOR RELIEF

**Violation of West Virginia Controlled Substances Act; W.Va. Code Section § 55-7-9
(Against Supply Chain Defendants)**

1558. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein, and further alleges:

1559. The Supply Chain Defendants illegally, wrongfully, and intentionally contributed to the opioid epidemic in the state of West Virginia through repeated intentional violations of various provisions of the West Virginia Uniform Controlled Substances Act and through reckless disregard to the safety and wellbeing of the citizens of Cabell County and the City of Huntington.

1560. The Supply Chain Defendants intentionally failed to meet or otherwise misrepresented their compliance with the requirements of W.Va. Code § 60A-8-1 et seq. and otherwise intentionally violated the West Virginia Uniform Controlled Substances Act.

1561. The Supply Chain Defendants intentionally failed to ensure their conduct conformed to industry standards, West Virginia law and other regulations.

1562. The Supply Chain Defendants intentionally violated industry standards, West Virginia law, and other regulations by regularly distributing obscene quantities of commonly-abused, highly addictive controlled substances to clients who were serving a customer base comprised of individuals who were abusing prescription medications, many of whom were addicted and whom can reasonably be expected to become addicted or to engage in illicit drug transactions.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

1563. The Supply Chain Defendants' intentional acts and omissions have led to the dispensing of controlled substances for non-legitimate medical purposes and fueling an opioid epidemic in the Plaintiffs' Community.

1564. The Supply Chain Defendants' intentional acts and omissions supplied millions of doses of commonly abused, highly addictive controlled substances that supported the demands of pain clinics that provided highly addictive prescription pain killers to individuals with no medical evidence supporting the prescription.

1565. The Supply Chain Defendants' intentional acts and omissions fueled countless prescriptions that were primarily filled to divert the medication to illegal purposes.

1566. The Supply Chain Defendants' intentional violations of West Virginia law make them liable for all the damages which are sustained there from W.Va. Code Section 55-7-9.

1567. The Supply Chain Defendants' intentional acts and omissions have proximately caused and substantially contributed to damage suffered by the Plaintiffs and created conditions which contribute to the violation of West Virginia laws by others.

1568. The Supply Chain Defendants' intentional acts and omissions have proximately caused and substantially contributed to damages suffered by the Plaintiffs and were in violation of the customs, standards and practices within Defendants' own industries.

1569. Upon information and belief, the Defendants continue to intentionally violate West Virginia laws and regulations, United States laws and regulations, and Defendants' industry customs, standards and practices which continue to proximately cause substantial damages to Plaintiff.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

SIXTH CLAIM FOR RELIEF

Unjust Enrichment

(Against Supply Chain Defendants, National Pharmacies, Purdue Officers and Directors, and PBMs)

1570. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein, and further alleges

1571. As an expected and intended result of their conscious wrongdoing as set forth in this Complaint, Defendants have profited and benefited from the increase in the distribution and purchase of opioids within Plaintiffs' Community, including from opioids foreseeably and deliberately diverted within and into Plaintiffs' Community.

1572. Unjust enrichment arises not only where an expenditure by one party adds to the property of another, but also where the expenditure saves the other from expense or loss.

1573. Plaintiffs have expended substantial amounts of money in an effort to remedy or mitigate the societal harms caused by Defendants' conduct.

1574. These expenditures include the provision of healthcare services and treatment services to people who use opioids.

1575. These expenditures have helped sustain Defendants' businesses.

1576. Plaintiffs have conferred a benefit upon Defendants by paying for Defendants' externalities: the cost of the harms caused by Defendants' improper distribution practices.

1577. Defendants were aware of these obvious benefits, and their retention of the benefit is unjust.

1578. Plaintiffs have paid for the cost of Defendants' externalities and Defendants have benefited from those payments because they allowed them to continue providing customers with a high volume of opioid products. Because of their deceptive marketing of prescription opioids, Marketing Defendants obtained enrichment they would not otherwise have obtained. Because of

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

their conscious failure to exercise due diligence in preventing diversion, Defendants obtained enrichment they would not otherwise have obtained. The enrichment was without justification and Plaintiffs lack a remedy provided by law.

1579. Defendants have unjustly retained benefits to the detriment of Plaintiffs, and Defendants' retention of such benefits violates the fundamental principles of justice, equity, and good conscience.

1580. Defendants' misconduct alleged in this case is ongoing and persistent.

1581. Defendants' misconduct alleged in this case does not concern a discrete event or discrete emergency of the sort a political subdivision would reasonably expect to occur and is not part of the normal and expected costs of a local government's existence. Plaintiffs allege wrongful acts which are neither discrete nor of the sort a local government can reasonably expect.

1582. Plaintiffs have incurred expenditures for special programs over and above Plaintiffs' ordinary public services.

1583. Plaintiffs seek an order compelling Defendants to disgorge all unjust enrichment to Plaintiffs; and awarding such other, further, and different relief as this Honorable Court may deem just.

SEVENTH CLAIM FOR RELIEF

**Civil Conspiracy
(Against Supply Chain Defendants)**

1584. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein, and further alleges:

1585. Defendants engaged in a civil conspiracy in their unlawful and tortious marketing of opioids and/or distribution of opioids into West Virginia and Plaintiffs' Community as set forth herein.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

1586. Defendants engaged in a civil conspiracy to commit fraud and misrepresentation in conjunction with their unlawful marketing of opioids and/or distribution of opioids into West Virginia and Plaintiffs' Community.

1587. Defendants unlawfully failed to act to prevent diversion and failed to monitor for, report, and prevent suspicious orders of opioids.

1588. The Marketing Defendants further unlawfully marketed opioids in the West Virginia and Plaintiffs' Community in furtherance of that conspiracy.

1589. Defendants' conspiracy and acts in furtherance thereof are alleged in detail in this Complaint, including, without limitation, in Plaintiffs' Counts for violations of RICO.

1590. Defendants acted with a common understanding or design to commit unlawful acts, as alleged herein, and acted purposely, without a reasonable or lawful excuse, which directly caused the injuries alleged herein.

1591. Defendants' actions demonstrated both malice and also aggravated and egregious fraud. Defendants engaged in the conduct alleged herein with a conscious disregard for the rights and safety of other persons, even though that conduct had a great probability of causing substantial harm. The Marketing Defendants' fraudulent wrongdoing was done with a particularly gross and conscious disregard.

1592. Defendants conduct in furtherance of the conspiracy described herein was not mere parallel conduct because each Defendant acted directly against their commercial interests in not reporting the unlawful distribution practices of their competitors to the authorities, which they had a legal duty to do. Each Defendant acted against their commercial interests in this regard due to an actual or tacit agreement between the Defendants that they would not report each other to the authorities so they could all continue engaging in their unlawful conduct.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

1593. Defendants' conspiracy, and Defendants' actions and omissions in furtherance thereof, caused the direct and foreseeable losses alleged herein.

1594. Defendants acted with actual malice because Defendants acted with a conscious disregard for the rights and safety of other persons, and said actions had a great probability of causing substantial harm.

1595. Defendants' misconduct alleged in this case is ongoing and persistent.

1596. Defendants' misconduct alleged in this case does not concern a discrete event or discrete emergency of the sort a political subdivision would reasonably expect to occur and is not part of the normal and expected costs of a local government's existence. Plaintiffs allege wrongful acts which are neither discrete nor of the sort a local government can reasonably expect.

1597. Plaintiffs have incurred expenditures for special programs over and above Plaintiffs' ordinary public services.

1598. Plaintiffs seek all legal and equitable relief as allowed by law, including *inter alia* injunctive relief, restitution, disgorgement of profits, compensatory and punitive damages, and all damages allowed by law to be paid by the Defendants, attorney fees and costs, and pre-and post-judgment interest.

EIGHTH CLAIM FOR RELIEF

**Punitive Damages
(Against All Defendants)**

1599. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein, and further alleges as follows:

1600. Plaintiffs are entitled to punitive damages under West Virginia Law if the Plaintiffs establish that Defendants' actions were the result of the conduct that was carried out by the

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

Defendants with actual malice toward the plaintiffs and/or a conscious, reckless and outrageous indifference to the health, safety and welfare of the plaintiffs and others.⁶³¹

1601. Defendants were selling and/or manufacturing dangerous drugs statutorily categorized as posing a high potential for abuse and severe dependence. Thus, Defendants knowingly traded in drugs that presented a high degree of danger if prescribed incorrectly or diverted to other than legitimate medical, scientific or industrial channels. Because of the severe level of danger posed by, and indeed visited upon the Plaintiffs' Community by, these dangerous drugs, Defendants owed a high duty of care to ensure that these drugs were only used for proper medical purposes. Defendants chose profit over prudence and the safety of the community, and an award of punitive damages is appropriate as punishment and a deterrence.

1602. By engaging in the wrongful conduct described herein above, Defendants engaged in willful misconduct and exhibited an entire want of care that would raise the level of actual malice and/or a conscious, reckless and outrageous indifference to the health, safety and welfare of the Plaintiffs and others.

PRAAYER FOR RELIEF

1603. Plaintiffs respectfully request that this Court enter an order of judgment granting all relief requested in this Joint and Third Amended Complaint, and/or allowed at law or in equity, including:

- a. abatement of the nuisance;
- b. actual damages;
- c. treble or multiple damages and civil penalties as allowed by statute;
- d. punitive damages;

⁶³¹ W. Va. Code § 55-7-29.

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

- e. exemplary damages;
- f. disgorgement of unjust enrichment;
- g. equitable and injunctive relief in the form of Court-enforced corrective action, programs, and communications;
- h. forfeiture disgorgement, restitution and/or divestiture of proceeds and assets;
- i. attorneys' fees;
- j. costs and expenses of suit;
- k. pre- and post-judgment interest; and
- l. such other and further relief as this Court deems appropriate.

Dated July 19, 2019

Respectfully submitted,

THE CITY OF HUNTINGTON and CABELL COUNTY, By Counsel:

THE CITY OF HUNTINGTON

/s/Charles R. "Rusty" Webb

Charles R. "Rusty" Webb (WVSB No. 4782)
THE WEBB LAW CENTRE, PLLC
716 Lee Street, East
Charleston, West Virginia 25301
Telephone: (304) 344-9322
Facsimile: (304) 344-1157
rusty@rustywebb.com

Joseph F. Rice
Anne McGinness Kearse (WVSB No. 12547)
MOTLEY RICE LLC
28 Bridgeside Blvd.
Mount Pleasant, SC 29464
Tel: 843-216-9000
Fax: 843-216-9450
jrice@motleyrice.com
akearse@motleyrice.com

CABELL COUNTY

/s/ Paul T. Farrell, Jr.

Paul T. Farrell, Jr. (WVSB Bar No. 0070257)
Bert Ketchum
**GREENE, KETCHUM, FARRELL,
BAILEY & TWEEL, LLP**
419 - 11th Street (25701)/ P.O. Box 2389
Huntington, West Virginia 25724-2389
Tel.: 800-479-0053 or 304-525-9115
Fax: 304-529-3284
paul@greeneketchum.com
bert@greeneketchurn.com

Anthony J. Majestro
POWELL & MAJESTRO, PLLC
405 Capitol Street, Suite P-1200
Charleston, WV 25301
Tel.: 304-346-2889
Fax: 304-346-2895
amajestro@powellmajestro.com

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

Linda Singer
MOTLEY RICE LLC
401 9th Street NW, Suite 1001
Washington, DC 20004
Tel: 202-232-5504
Fax: 202-386-9622
lsinger@motleyrice.com

*Additional Counsel for Cabell County
Commission*

Russell W. Budd
J. Burton LeBlanc, IV
Christine C. Mansour
BARON & BUDD, P.C.
3102 Oak Lawn Avenue, Suite 11 00
Dallas, TX 752 19
Tel.: 214-521-3605
Fax: 214-520-1181
rbudd@baronbudd.com
bleblanc@baronbudd.com
cmansour@baronbudd.com

Roland K. Tellis
Mark P. Pifko
BARON & BUDD, P.C.
15910 Ventura Boulevard, Suite 1600
Los Angeles, CA 91436
Tel.: 818-839-2333
Fax: 818-986-9698
rtellis@baronbudd.com
mpifko@baronbudd.com

Peter J. Mougey
Troy Rafferty
Page A. Poerschke
Laura S. Dunning
Neil E. "Ned" McWilliams
Jeffrey Gaddy
**LEVIN, PAPANTONIO, THOMAS,
MITCHELL, RAFFERTY &
PROCTOR, P.A.**
316 S. Baylen Street, Suite 600
Pensacola, FL 32502-5996
Tel.: 850-435-7068
Fax: 850-436-6068
pmougey@levinlaw.com
trafferty@levinlaw.com
ppoerschke@levinlaw.com
ldunning@levinlaw.com
nmcwilliams@levinlaw.com
jgaddy@levinlaw.com

CONFIDENTIAL: FILED UNDER SEAL/SUBJECT TO PROTECTIVE ORDER

Michael J. Fuller, Jr. (Ohio Bar No. 0090250)
Amy Quezon (Ohio Bar No. 0091798)
McHUGH FULLER LAW GROUP, PLLC
97 Elias Whiddon Rd.
Hattiesburg, MS 39402
Tel.: 601-261-2220
Fax: 601-261-2481
mike@mchughfuller.com
amy@mchughfuller.com

Michael A. Woelfel
Woelfel & Woelfel
801 Eighth Street
Huntington, WV 25701
Tel.: 304-522-6249
Fax: 304-522-9282